DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

P920023

# Memorandum

Date MAY 6 1996

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of American Medical Systems
Urolume™ Endourethral Prosthesis for Urethral Strictures - ACTION

To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

for Susan Alpert, Ph.D., M.D.

Attachments

Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by James P. Seiler, CDRH, HFZ-470, 11/03/95, 594-2194

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DRAFT

FOOD AND DRUG ADMINISTRATION

DOCKET NO.

APPLICANT: American Medical Systems;

PREMARKET APPROVAL OF: Urolume™ Endourethral Prosthesis.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by American Medical Systems, Minnetonka, MN, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of Urolume™ Endourethral Prosthesis. After reviewing the recommendation of the Gastroenterology and Urology Devices Advisory Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on MAY - 6 1996, of the approval of the application.

DATE: Petitions for administrative review by _____.

ADDRESS: Address written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Drive, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James Seiler
Center for Devices and Radiological Health (HFZ-470)
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850
301-594-1195.

SUPPLEMENTARY INFORMATION: On June 14, 1993, American Medical Systems, Minnetonka, MN 55343, submitted to CDRH an application for premarket approval of the Urolume™ Endourethral Prosthesis. The device is intended for use in men to relieve urinary obstruction secondary to recurrent benign bulbar urethral strictures less than 3.0 cm in length located distal to the external sphincter and proximal to the bulbar scrotal junction. The UroLume™ prosthesis is not intended as an initial treatment for bulbar urethral strictures nor for the treatment of strictures outside the bulbar urethra. The UroLume™ prosthesis is an alternative treatment for the patient in whom previous treatment methods (dilation, urethrotomy or urethroplasty) have been unsuccessful (i.e., treatment was not effective initially in relieving stricture disease or there has been recurrence of stricture formation necessitating further treatment).

B

On January 20, 1995, the Gastroenterology and Urology Devices Advisory Panel, an FDA advisory panel, reviewed and recommended approval of the application.

On MAY - 6 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

## OPPORTUNITY FOR ADMINISTRATIVE REVIEW

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA

4

will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before _____, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under the Federal Food, Drug, and Cosmetic Act (s. 515(d), 21 U.S.C. 360e(d), 360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated:_____.

_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 6 1996

Lisa L. Pritchard
Senior Regulatory Affairs Specialist
American Medical Systems, Inc.
Pfizer Hospital Products Group
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: P920023
UroLume™ Endourethral Prosthesis for Urethral Strictures
Filed: June 14, 1993
Amended: July 15, 22, 30, and October 12, 1993;
January 31, February 23, April 26, June 6 and 30, August 15,
October 28, November 16, and December 9, 1994;
August 16, October 11 and 31, 1995; March 19, and April 3, 1996

Dear Ms. Pritchard:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the UroLume™ Endourethral Prosthesis for Urethral Strictures (referred to as UroLume™ hereinafter). The UroLume™ is intended for use in men to relieve urinary obstruction secondary to recurrent benign bulbar urethral strictures less than 3.0cm in length located distal to the external sphincter and proximal to the bulbar scrotal junction. The UroLume™ is not intended as an initial treatment for bulbar urethral strictures nor for the treatment of strictures outside the bulbar urethra. The UroLume™ is an alternative treatment for the patient in whom previous treatment methods (dilation, urethrotomy or urethroplasty) have been unsuccessful (i.e., treatment was not effective initially in relieving stricture disease or there has been recurrence of stricture formation necessitating further treatment). We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

In addition to meeting the enclosed post-approval requirements under the authority of 21 CFR 814.44(e), the post-approval reports should include annual progress reports on the post-approval studies outlined below and recommended by FDA and the Gastroenterology/Urology Devices Advisory Panel during the January 20, 1995, meeting regarding issues not fully addressed by the clinical trial.

The first post-approval study should further assess long-term hyperplastic tissue growth inside the stent, retreatment, and stone formation for an additional 5 years in all patients enrolled in the original study.

The second post-approval study on 100 new patients followed for 2 years should assess urinary tract infection, incontinence, post-void dribbling, quality of life, retreatments and 1-year sexual function data. The long-term data from these studies should be reflected in the labeling (via a supplement) when the post-approval study is completed. The final condition of approval is to develop a method to identify the patients that receive the device.

Expiration dating for this device has been established and approved at 3 years.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

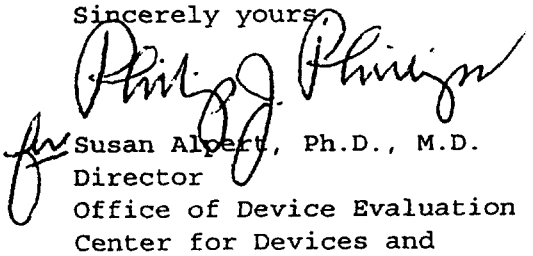
You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. James Seiler at (301) 594-2194.

Sincerely yours,



for Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

(1) Conditions of Approval

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

AMERICAN MEDICAL SYSTEMS'
UROLUME™ ENDOURETHRAL PROSTHESIS

I. GENERAL INFORMATION

| | |
|---|---|
| DEVICE GENERIC NAME: | Permanent Bulbous Urethral Stent |
| DEVICE TRADE NAME: | UroLume™ Endourethral Prosthesis |
| APPLICANT NAME: | American Medical Systems, Inc.<br>Pfizer Hospital Products Group<br>10700 Bren Road West<br>Minnetonka, MN 55343 |
| PREMARKET APPROVAL (PMA) APPLICATION NUMBER: | P920023 |
| DATE OF PANEL RECOMMENDATION: | January 20, 1995 |
| DATE OF NOTICE OF APPROVAL TO THE APPLICANT: | May 6, 1996 |

## II. INDICATIONS FOR USE

The American Medical Systems UroLume™ Endourethral Prosthesis (hereinafter called UroLume™) is intended for use in men to relieve urinary obstruction secondary to recurrent benign bulbar urethral strictures less than 3.0 cm in length located distal to the external sphincter and proximal to the bulbar scrotal junction.

The UroLume™ is not intended as an initial treatment for bulbar urethral stricture disease nor for the treatment of strictures outside the bulbar urethra. The UroLume™ is an alternative treatment for the patient in whom previous treatment methods (dilation, urethrotomy, or urethroplasty) have been unsuccessful (i.e., treatment was not effective initially in relieving stricture disease or there has been recurrence of stricture formation necessitating further treatment).

## III. DEVICE DESCRIPTION

The UroLume™ is a braided mesh cylinder designed to radially expand after deployment to hold open sections of the urethra that obstruct the flow of urine. The stent is made from Elgiloy®, a non-ferromagnetic metal alloy composed of cobalt, chromium, nickel, molybdenum, iron, and trace amounts of manganese, carbon, silicon, phosphorous, sulfur, and beryllium. The stent is delivered cystoscopically using a specially designed insertion tool intended to deploy the prosthesis in a controlled manner. Upon deployment, the stent expands in diameter and shortens in length. Its final dimensions are determined by the size and resistance of the urethral lumen. The stent is supplied sterile in 2, 2.5, and 3 cm lengths and opens to a maximum expanded diameter of 14 mm (42 French).

The prosthesis is sterile and packaged pre-loaded in a specialized, disposable delivery tool. The delivery tool consists of two concentric stainless steel tubes with an outer diameter of approximately 7 mm (21 French). The tool includes two security buttons; the first button partially deploys the prosthesis without complete release from the retractable clamp, while the second security button fully retracts the delivery tool's outer shaft, opens the retaining clamp and completely releases the prosthesis. The outer shaft has windows to allow visualization of the urethra and the constrained prosthesis.

## IV. CONTRAINDICATIONS

The UroLume™ is contraindicated for patients with:

1. meatal urethral strictures which cannot be opened to 26 Fr by dilation, urethrotomy, or meatotomy;

2. strictures of the external sphincter;

3. active urinary tract infection (UTI);

4. other urethral conditions requiring transurethral manipulations within 1 month of UroLume™ placement;

5. infected suppurating strictures;

6. a fistula at the proposed prosthesis location;

7. urethral squamous cell carcinoma; or,

8. perineal urethrostomy.

Refer to the labeling for a list of the warnings and precautions.

## V. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The following adverse events, occurred during the study of the UroLume™ for the treatment of urethral strictures:

Of the 173 patient study cohort, 88% (153/173) of the patients reported post void dribbling (PVD), 71% (122/173) of the patients reported pain/discomfort, 57% (99/173) of the patients reported urinary incontinence, and 44% (76/173) of the patients reported hematuria. These numbers reflect the total number of patients reporting a complication, regardless of severity or pretreatment status of these complaints. The majority of patients who reported incontinence rated their condition as mild (on a scale of mild, moderate, and marked).

Forty-one percent (71/173) of the patients experienced UTI at some time after UroLume™ implantation. UTI is a known complication of urethral stricture disease, and 48% (83/173) of the study population had a history of UTI prior to implantation.

Squamous cell metaplasia was reported in 3% (5/173) of the patients. Four of these patients had a previous skin graft urethroplasty. Two of these patients required stent removal. Migration occurred in 5% (8/173) of the patients; six device migrations occurred within 6 weeks of UroLume™ implant. Encrustation of the UroLume™ occurred in 3% (5/173) of the patients, four of whom required standard surgical treatment to remove the encrustation.

There were 10 patient deaths during the study: one due to urethral squamous cell carcinoma; two due to myocardial infarction; four due to cerebral vascular accidents; one due to malignant fibrous histiocytoma; one due to congestive heart failure; and one due to an intraventricular cerebral hemorrhage. None of the deaths were considered to be device related; however, based on the information available, a causal relationship between the UroLume™ and the case of squamous cell carcinoma cannot be completely ruled out.

Of the 173 patients, 28 (16%) required additional treatment (catheterization along with resection, laser ablation, dilation, additional stents, or combination of these methods)

for stricture recurrence either inside or adjacent to the stented region within 2 years of device implantation.

## VI. ALTERNATE PRACTICES AND PROCEDURES

A variety of procedures are used in the treatment of recurrent urethral strictures. The most common are repetitive dilation, urethrotomy, and urethroplasty.

Dilation involves a series of treatments in which the strictured section of the urethra is gently stretched by passage of progressively larger instruments[1, 2, 3], on a gradual basis, to minimize tissue disruption and further scarring. Current practice involves the use of bougies, sounds, filiform catheters and followers, soft catheters, or balloon catheters[1, 4-9].

Visual internal urethrotomy (VIU) involves incision through the dense ring of strictured scar tissue into the adjacent, more-elastic, normal tissue, allowing the ring to open, thus widening the urethral lumen.

Urethroplasty is surgical reconstruction of the urethra, and may involve a number of separate surgical procedures. In current practice, urethroplasty is usually reserved for treatment of the most difficult strictures; those which are impassable, or complicated by sepsis, abscess, fistula, or calculi; those which are refractory to treatment by dilation or urethrotomy; and those which follow major soft tissue disruption resulting from severe trauma[1, 10].

## VII. MARKETING HISTORY

The UroLume™ device is available throughout most of Europe, Canada, the Middle East, Africa, Latin America, Australia, and the Pacific Rim. To date, the UroLume™ has not been withdrawn from any market for any reason related to the safety or effectiveness of the device.

## VIII. SUMMARY OF PRECLINICAL STUDIES

### A. Biocompatibility

Biocompatibility tests (USP Class VI) were conducted in accordance with standard methodologies, and included: muscle implantation in rabbits (7, 32, 90, and 180 days), hemolysis, cytotoxicity, acute systemic toxicity in mice, intracutaneous irritation in rabbits, pyrogenicity, and chemical analysis. The results showed no significant toxicity.

The UroLume™ was also implanted in the urethra of four male dogs which were sacrificed and examined: two dogs at 6 months, one at 9 months, and one at 16 months. There were no significant systemic or local toxic effects. Interstitial nephritis, chronic prostatitis, and bronchial adenocarcinoma were observed but not attributed to the UroLume™.

Another study involved device implantation in the urethra of 10 female sheep. The sheep were sacrificed: two at 3 months, four at 6 months, and four at 12 months. No significant pathological changes were observed in the sheep at 3 months, but histological analysis did show mild sub-acute inflammation, hemorrhage, and pressure necrosis adjacent to the stent. The 6 and 12 month results included angiogenesis in the submucosa, acute to chronic inflammation, hemorrhage, and hyperplasia of the transitional epithelium in addition to pressure necrosis, fibrous tissue, and thick mineral deposits. It was concluded that the effects observed were not attributable to the toxicity of the materials used in the UroLume™, but may be due to the chronic irritation, pressure, and trauma caused by its presence.

B. Laboratory Studies

Mechanical tests were performed on sterilized samples of the UroLume™ to evaluate the effects of constriction, elongation, severe elongation, and corrosion. The constriction test indicated that the device could withstand constriction to 25% of its original diameter. The elongation test demonstrated the device could be stretched and compressed by 25% of its original length for 2.8 million cycles with three sample devices. The severe elongation test showed that the UroLume™ could withstand stretching and compression by 50% of its original length through 5.1 million cycles with three sample devices. The corrosion test demonstrated that no appreciable corrosion to the surface of the UroLume™ occurs when exposed to saline, artificial urine, or air with six sample devices.

## IX. SUMMARY OF CLINICAL INVESTIGATIONS

The UroLume™ clinical investigation was conducted in accordance with an approved investigational device exemptions (IDE) application (G880189). The investigation began on April 26, 1989, and active patient enrollment ceased by February 22, 1993. The enrollment included 179 patients at 12 investigational sites in the United States. Six of these patients were enrolled outside of the protocol. Since the stents for these six patients were not placed in the bulbar urethra, these patients were excluded from the analysis. Accordingly, the study population used for analysis consists of 173 patients. Approximately 35% (60/173) of the insertion procedures were performed at three investigational sites.

A. Objectives

The objectives of the UroLume™ clinical investigation were to: 1) demonstrate that the device can be properly inserted and positioned endoscopically without adverse sequelae; 2) demonstrate that the device can hold open a urethral stricture; 3) demonstrate that the device is epithelialized completely and without adverse sequelae; 4) determine the rate of stricture recurrence and device failure; and 5) demonstrate that the anticipated adverse events are acceptably low and can be managed without long term sequelae.

The hypotheses of the study were that 1) peak and mean urinary flow rates would remain increased for 1 year; 2) symptoms of urethral stricture disease would remain reduced for 1 year; and 3) the frequency of retreatment for urethral stricture disease would be reduced for a 1 year period.

B. Inclusion and Exclusion Criteria

The inclusion criteria permitted enrollment of males ≥ 21 years old with benign bulbar urethral strictures ≤ 5 cm long which could be dilated to 26 French, who were good candidates for urethroplasty and had failed previous treatments. The enrollment criteria excluded patients with strictures near the external sphincter (stent implantation could compromise urinary continence) and patients with active UTI. These criteria helped to ensure the enrollment of a study cohort with homogeneous pretreatment characteristics (to allow for pooling) which would be representative of the future labeled target population. After an unanticipated adverse event that resulted in a patient death in another UroLume™ clinical trial, the study protocol was modified to exclude patients with thrombocytopenia, hemophilia, and those receiving blood products for bleeding disorders.

C. Protocol

Immediately prior to stent insertion, the protocol required investigators to perform dilation (to 26 French), urethrotomy (3 incisions), or both dilation and urethrotomy at the stricture site. The UroLume™ was then implanted under visual guidance, using multiple, overlapping stents if needed, to bridge the strictured area.

Peak and mean urinary flow rates, total and individual symptom scores, urine cultures to determine UTI status, restricture and retreatment rates, and adverse events were assessed. The stent was observed by urethroscopy at each follow-up starting at 6 months; this permitted the determination of any evidence of obstruction, irritation, migration, erosion, encrustation, or mechanical problems, as well as the extent of epithelialization. The follow-up schedule was: 6 weeks, 6 months, 12 months, 24 months, and yearly until PMA approval.

D. Critiques of Study and Analysis

Although an active control group clearly would have been desirable, use of the patient as his own control was ultimately deemed acceptable. Use of such a within-patient, historical control is appropriate when the condition under study is irreversible, and not subject to the placebo effect or improvement without intervention. Urethral stricture disease meets these criteria, as is evidenced by the lack of improvement seen in the study patients after repeated dilations, urethrotomies, and urethroplasties (patients had an average of 19.1 stricture treatments prior to study enrollment).

Since all patients had failed treatment prior to UroLume™ implantation, an analysis comparing retrospectively gathered preinsertion treatment data with postinsertion treatment data was conducted. Two comparison groups were developed as a result: a

group of 106 patients who had complete treatment history from 1 year prior to stent insertion through the year following stent insertion, and a secondary cohort of 85 patients which had complete treatment history documented for the 2-year period prior to implantation through the 2-year period after implantation. These groups were used to compare the stricture treatment rates prior to and following stent implantation.

A large number of protocol deviations were reported during the clinical investigation. The deviations included alterations in the patient selection criteria, missing or significantly late follow-up, and alterations in the methods of device insertion or evaluation.

To evaluate the effects of these deficiencies on the study population, two additional specific patient cohorts were derived from the study population. These cohorts reflect (1) patients with complete prospective study data through 1 year of follow-up and (2) patients with complete prospective study data through 2 years of follow-up. Patients in these cohorts had all data available for analysis, met the patient selection criteria, had no deviations from the implantation procedure specified in the protocol, and met their follow-up visits within 60 days of the scheduled date. The results indicate that the two cohorts, as well as the patients with procedural deviations, experienced similar results as the overall patient population. Therefore, the data presented herein are generally confined to the overall patient population, except where otherwise noted.

E. Statistical Analysis

Pooling the data between investigational sites was justified based on statistical comparisons of patient demographics and study results. Although significant differences were noted between institutions for some variables, these characteristics did not significantly affect the major effectiveness outcome variables (peak and adjusted peak flow, mean and adjusted mean flow, and total symptom score).

As discussed previously, because of deficiencies in the study design and execution, it was necessary to evaluate selected patient cohorts: (1) a 1 year cohort (1YC) and a 2 year cohort (2YC) which only included patients with complete follow-up data, none of whom were procedural or patient selection deviations; and (2) a 1 year retreatment cohort (1YC") and a 2 year retreatment cohort (2YC") which consisted of patients with complete treatment data prior to stent implantation and after implantation. The retreatment cohorts (1YC" and 2YC") were derived specifically to evaluate whether the retreatment rate following UroLume™ implantation was reduced compared to retreatment rates following dilation and/or urethrotomy. The derivation of these cohorts is shown in Table 1.

**Table 1 - Patient Accountability**

| Flow/Symptom Cohorts | 1YC | 2YC |
|---|---|---|
| Total Enrolled | 173 | 173 |

| Retreatment Cohorts | 1YC" | 2YC" |
|---|---|---|
| Total Enrolled | 173 | 173 |

| Flow/Symptom Cohorts | 1YC | 2YC |
|---|---|---|
| Follow-up Not Attended | 40 | 74 |
| Incomplete Data | 39 | 33 |
| Follow-up > ±60 days | 31 | 30 |
| Selection Deviations Only | 11 | 3 |
| Ineligible for Follow-up | NA | 9 |
| Number in Cohort | 52 | 24 |

| Retreatment Cohorts | 1YC" | 2YC" |
|---|---|---|
| Tx History Not Requested | 10 | 10 |
| Incomplete Prior Tx History Available | 34 | 55 |
| Tx History Not Received | 13 | 13 |
| Lost to Follow-up | 5 | 5 |
| Urethroplasty last Tx | 5 | 5 |
| Available to Analyze | 106 | 85 |

As the table indicates, patients whose last treatment was urethroplasty were excluded from the retreatment analysis because it was desired to compare the retreatment rate following UroLume™ implantation with the retreatment rate following only dilation and/or urethrotomy.

Experience with the UroLume™ for urethral strictures is available through 4 years of follow-up, although there are few patients at the 3 and 4 year intervals. For effectiveness analyses, the 1YC, 2YC, 1YC", 2YC" and overall patient populations were evaluated. Safety analyses included all patients regardless of their classification as deviations, completeness of their data, or range of follow-up (intent to treat cohort).

F. Statistical Tests

Depending on the type of data, different statistical tests were used. Analysis of variance (ANOVA) and paired t-tests were used for the continuous variables of peak and mean flow (including flows adjusted by the square root of the volume voided to adjust for large bladder output), and total symptom score. The Pearson's Chi-square ($\chi^2$) statistic was used for categorical variables: etiology, previous UTI, location of stricture, etc. The Kruskal-Wallis test was used for independent patient groups with less than 5 occurrences. The Wilcoxan sign rank test was used to compare pre-insertion and post-insertion individual symptom scores. The Kruskal-Wallis non-parametric one-way ANOVA was used to evaluate differences between variables with continuous, but skewed distributions, such as number of previous dilations or urethrotomies. Finally, logistic regression was used to evaluate the significance of study variables on safety and effectiveness.

G. Pretreatment Characteristics

The patients in the study had a mean age of 52 (range 17-92). The study group had been treated a mean of 12.7 years (range 1-64 years) for their stricture disease and had experienced a mean of 19.1 prior treatments (range 1-110+). Prior history of UTI was noted for 48% of the patients.

Prior to stent implantation, the mean peak urinary flow rate was 9.8 cc/sec, and the mean total symptom score was 12.7 out of a possible score of 30. Of all the components of the symptom score, poor flow was reported the most often (99% of the patients at preinsertion). The prevalence of other reported symptoms at preinsertion were prolonged voiding time (83%); urinary frequency (80%); incomplete emptying (73%); hesitancy (72%); nocturia (72%); PVD (66%); two-stage voiding (57%); and painful urination (40%).

The stricture opening procedure used at the time of stent insertion was dilation in 38%, urethrotomy in 35%, and both methods in 27% of the study population. A total of 237 devices were used to treat the 173 patient group, but malpositioned and withdrawn stents left a total of 224 devices deployed. More 3 cm stents (n=150) were used than 2 cm (n=66) devices, and only eight 2.5 cm devices were used. The stricture was completely covered at the end of the initial insertion procedure in all but 14 patients. Eleven percent (19/173) of the patients needed additional stents inserted post initial insertion.

H. Effectiveness Analysis

The effectiveness variables include average peak and mean urinary flow rates (including Liverpool Nomogram[11] analysis - average flow rate curves based on empirical data), total and individual symptom scores, and the retreatment rate.

I. Effectiveness Analysis - Urinary Flow Rate

In the patient population studied, the UroLume™ maintained increased peak and mean urinary flow rates 2 years after insertion. The mean peak flow rate increased from 9.8 cc/sec at baseline, to 23.6 cc/sec at 24 months ($p < 0.001$) and declined at 3 years (20.7 cc/sec) and 4 years (15.7 cc/sec), however these results were still statistically improved compared to baseline ($p < 0.001$ and $p < 0.007$, respectively).

Similar statistically significant and clinically meaningful improvements were noted for the adjusted peak flow rate (calculated by dividing peak flow by the square root of the volume voided to eliminate the effect of urine volume on the peak flow measurement)[12].

As Table 2 below indicates, the percentage of patients that met the 95th percentile of their age and volume adjusted peak flow rates as defined by the Liverpool Nomogram improved significantly, from only 29% at preinsertion to greater than 73% at any follow-up period for all patients. Similar results occurred for the 1YC and 2YC cohorts.

**Table 2 - Nomogram Results (% Patients in 95th percentile Liverpool Nomogram)**

| Follow-up | All patients | One Year Cohort (1YC) | Two Year Cohort (2YC) |
|---|---|---|---|
| Pre-Insertion | 32.9 ( 49/149) | 36.5 (19/52) | 29.2% ( 7/24) |

| Follow-up | All patients | One Year Cohort (1YC) | Two Year Cohort (2YC) |
|---|---|---|---|
| 6 week | 90.0 (135/150) | 94.2 (49/52) | 91.7% (22/24) |
| 6 months | 82.4 (117/142) | 80.8 (42/52) | 87.5% (21/24) |
| 12 months | 85.9 (110/128) | 84.6 (44/52) | 83.3% (20/24) |
| 24 months | 80.2 ( 65/ 81) | NA | 79.2% (19/24) |
| 36 months | 73.2 ( 41/ 56) | NA | NA |
| 48 months | 84.6 ( 11/ 13) | NA | NA |

J. Effectiveness Analysis - Symptom Scores

The symptom score used was prospectively developed by the applicant specifically for this study. The score assessed the following 10 symptoms: hesitancy, poor flow, incomplete emptying, frequency, nocturia, painful urination, hematuria, two-stage voiding, PVD, and prolonged voiding time. Each individual score was graded according to the perceived severity (weighted on the following scale: absent=0, mild=1, moderate=2, and marked=3). The total symptom score at follow-up is composed of the sum of the weighted individual scores; the possible scores range from 0 to 30.

Total symptom score decreased from an average of 12.7 at baseline to 2.4 at 24 months ($p < 0.001$), 2.3 at 3 years ($p < 0.001$) and 1.8 at 4 years ($p < 0.001$). Similar results were seen with the 1 and 2 year cohorts. These data indicate that the symptomatic improvement following UroLume™ implantation is durable.

Individual symptom components of the symptom score indicate that symptomatic improvement was statistically significant ($p < 0.001$) for all individual symptoms at nearly every follow-up interval. The only exception was hematuria, which was not significantly affected by the device. While statistically significant improvements were noted for PVD, this symptom remains a problem (at mild or greater severity) for approximately 40% of the study patients at all follow-up intervals. Approximately 67% of the patients had PVD prior to implantation.

K. Effectiveness Analysis - Retrospective Retreatment Analysis

To determine if the rate of retreatment was reduced in the year following UroLume™ implantation, the treatment history in the period prior to UroLume™ implantation was compared to the treatment rate after implantation. Table 3 below summarizes the treatment data gathered from the two retreatment cohorts for whom complete treatment history was available 12 months prior to and 12 months following implantation (1YC"), and 24 months prior to and 24 months following the device implantation



17

(2YC"). Note that the treatment data prior to UroLume™ implantation were gathered retrospectively. As Table 3 demonstrates, the reduction in the total number of stricture treatments needed after UroLume™ implantation (regardless of proximity to the stent) was statistically significant and clinically meaningful.

**Table 3 - Retrospective Retreatment Data, Comparison to Post-Insertion Results**

| | 1YC" (106 Patients -12 Months) | | | 2YC" (85 Patients -24 Months) | | |
|---|---|---|---|---|---|---|
| | Pre | Post | Delta | Pre | Post | Delta |
| Average Treatments (Tx/year/patient) | 2.35 | 0.18 | -2.17 | 2.06 | 0.15 | -1.91 |
| Total Treatments | 249 | 19 | -230 | 350 | 25 | -325 |
| % Patients that Needed Retreatment | 74.5% (79/106) | 15.1% (16/106) | -59.4% p<.001 | 83.3% (71/85) | 20% (17/85) | -63.3% p<.001 |

When the entire patient population is considered, although there were 92 cases of hyperplasia reported within the stented portion of the urethra, 84% (145/173) of the study patients needed no further treatments during the course of the clinical investigation following UroLume™ implantation. Conversely, 16% (28/173) of patients required retreatment (catheterization along with resection, laser ablation, dilation, additional stents, or combination of these methods) within the area covered by the UroLume™ (17 patients) or adjacent to it (11 patients) during the entire study. In addition, 17 patients required treatment for strictures outside the stented region (5 of these 17 were also represented in the 28 mentioned above).

Therefore, the total retreatment rate, considering these additional 17 patients, was 23% (40/173); however, the need for retreatment outside of the stented region cannot be considered a failure of the stent itself.

Prognostic factors leading to retreatment included a large number of previous dilations (p=0.01) and incomplete stricture coverage at stent insertion (p=0.05). The retreatment rate was highest in patients with a history of urethroplasty (40% for urethroplasty patients vs. 11% for non-urethroplasty patients).

## L. Safety Analysis

Safety was assessed through physical examination and by questioning of all 173 patients by the investigators. Assessment measures included cystoscopy, urine culture, and the aforementioned direct and indirect questioning regarding complications between follow-up examinations.



18

Investigators specifically queried patients regarding four complications: pain/discomfort, hematuria, PVD, and incontinence. At both 12 and 24 months, the incidence of pain/discomfort of any severity was approximately 15%; the incidence of hematuria of any severity was approximately 10%; the incidence of PVD of any severity was approximately 50%; and the incidence of incontinence was approximately 25%. Since incontinence and PVD were neither clearly defined nor distinguished in the study protocol, these results may be biased by investigator and/or patient interpretation. For example, patient reports of incontinence may have been reported as PVD, and vice versa. For all four complications identified above, the incidence remained stable beyond 12 months, indicating a lack of any significant delayed complications.

While pain, hematuria, and PVD were all reduced in frequency and severity compared to preinsertion symptom assessment, there is no basis to compare the incidence of postinsertion incontinence. Assuming none of the patients had incontinence prior to implantation (worse case analysis), UroLume™ implantation is associated with an incontinence rate of approximately 28% at 1 year (70% of these were mild). Unfortunately, incomplete data were collected on the type of incontinence experienced. As Table 4 below indicates, stress incontinence was reported most frequently. The proportion of patients with moderate to marked incontinence sufficient to require management ranged from 33% to 50% at follow-up; management typically consisted of the use of pads or medical therapy. The reduced denominator in Table 4 reflects the limited number of subjects in whom the management of incontinence was reported.

**Table 4 - Type of Incontinence and the Need for Management**

| Incontinence Data | 6 weeks | 6 months | 12 months | 24 months |
|---|---|---|---|---|
| Reported cases | 40% (64/160) | 33% (49/149) | 28% (39/140) | 25% (24/94) |
| Type: *Stress* | 39 | 23 | 16 | 8 |
| *Urge* | 7 | 5 | 2 | 1 |
| *Non-Resistance* | 11 | 8 | 4 | 1 |
| *Not Described* | 7 | 13 | 17 | 14 |
| Need Incontinence Control (Moderate & Marked) | 47.8% (11/23) | 29% (4/14) | 50% (6/12) | 33% (1/3) |

Logistic regression analyses of complications noted at 12 months indicated that pain/discomfort was related to the number of insertion procedures (p=0.0033) and traumatic etiology of the stricture (p=0.0548). Hematuria was significantly related to the number of insertion procedures (p=0.0011). PVD had no prognostic factors evident, but incontinence was related to the method used to open the stricture; notably, moderate or marked incontinence was observed in 18% of the patients for whom the

stricture was opened with a combination of dilation and urethrotomy, but in only 6% of the patients whose strictures were opened by either dilation or urethrotomy. The significance of this apparent association is unclear.

In addition to the above information, data were also collected on painful urination, hematuria, and PVD as part of the 10-component symptom score and are summarized here since they are safety related. Note: while the symptom data were collected at the time of follow-up and reflected the patient's condition on the day of the follow-up examination, data on complications covered the time between follow-up examinations. As a result, the incidence of hematuria, for example, expressed as a symptom at a given follow-up versus hematuria expressed as a complication at that same follow-up visit will be different.

Logistic regression analysis indicated that the length of the stricture significantly affects (p=0.0466) painful urination at 12 months. While none of the patients with strictures < 1.0 cm long experienced painful urination, this was a problem for 10% of patients with 1.1-3.0 cm strictures, and for 20% of patients with longer strictures. Hematuria was most significantly affected (p=0.0470) by the number of stents at 12 months, i.e., only 3% of single stent patients had hematuria at 12 months, but 15% of the patients with multiple devices complained of hematuria at 12 months. No variables were found to be associated with PVD at 12 months.

Although the UroLume™ does effectively manage most of the effects of recurrent urethral stricture disease, it does not reduce the rate of UTI. Forty-one percent (71/173) of the study patients experienced UTI at some time during the study; 48% of the overall patient population had a history of UTI prior to implantation. The incidence of UTI increased at 6 months, and remained at 10% or greater through 3 years, with a high of 21% at 12 months postinsertion (Table 5). Patients with multiple stents had a statistically higher incidence of UTI (39% vs. 16%). Although the increase of UTI, especially at 12 months, raises the question of whether the UroLume™ may be a nidus for infection, these results must be balanced against the data in the literature indicating that patients with recurrent urethral stricture disease may have UTI rates as high as 30%[13].

**Table 5 - Incidence of UTI**

| Pre-insertion | Insertion | 6 weeks | 6 months | 12 months | 24 months | 36 months | 48 months |
|---|---|---|---|---|---|---|---|
| 9% (14/156) | 6% (6/105) | 7% (10/150) | 11% (15/135) | 21% (28/133) | 12% (10/83) | 10% (6/59) | 7% (1/14) |

Epithelialization of the UroLume™ was generally well underway by 6 months post-implantation, with 90% to 100% coverage estimated during cystoscopy in 68% (97/142) of the study patients. At 12 and 24 months, 90% and 95% of the patients had complete epithelialized stents. Regression analysis indicated that complete epithelialization was delayed in patients with longer prior treatment history,

yet occurred more rapidly in patients with a history of UTI and without a prior urethrotomy. The clinical reasons for these statistical findings are unclear.

UroLume™ migration was reported in eight patients; all but one of these occurred within 6 weeks of insertion. Two of these cases were attributed to manipulation of the device by the patient. An additional migration occurred during the insertion procedure.

Urinary retention occurred in nine patients; four of these cases occurred immediately after implantation and were managed with catheterization. The five remaining cases occurred between 6 weeks and 3 years, and necessitated either an additional stent, resection of tissue, or catheterization. Catheterization was required in 14 patients during the study (6 suprapubic, 8 foley); six of these were immediately post-operative.

Of the five cases of stone formation associated with the UroLume™, four required treatment by flushing or mechanical extraction. Three additional cases of urethral calculi were reported, none of which were attributed to the stent. Although the incidence of stone formation should theoretically be reduced with stent epithelialization, all reported cases of encrustation/stone formation occurred at or beyond 1 year, when epithelialization was generally complete.

Limited prostate specific antigen (PSA) data were available and demonstrated no significant difference between the preinsertion evaluation and the 1 and 2 year follow-up evaluations.

One case of squamous cell carcinoma and five cases of squamous cell metaplasia were reported. Four of these patients had previous urethroplasty skin grafts. The urethral stricture of the patient that developed squamous cell carcinoma was noted to have an atypical cauliflower-like appearance at preinsertion. By the 6 month follow-up, friable necrotic tissue was exuding from the ends of the stent. Biopsy at the time of device removal, 9 months postinsertion, was indicative of polypoid urethritis with squamous mucosa; also reported were some atypia and occasional mitotic figures. A lytic region discovered under CT scan and KUB film was histologically examined and determined to be squamous cell carcinoma. The patient received chemotherapy, but died 20 months postinsertion.

Since urethral stricture disease is one of the precursors for the development of urethral squamous cell carcinoma[14-19], it is unlikely that the stent was an etiological factor in this case. Nevertheless, the potential for squamous cell carcinoma and metaplasia must be factored into the UroLume™ risk assessment.

M. New Strictures

As the clinical report indicates, the UroLume™ does not prevent new urethral strictures from occurring. The development of new strictures was reported in 32%



21

(56/173) of patients, occurring proximal (n=23), distal (n=24), and at both ends (n=9) of the device.

N. Sexual Function Analysis

The pre-treatment sexual function data were not prospectively collected during the early phases of the clinical trial, so unfortunately, only a limited assessment of the effects of the UroLume™ on sexual function can be made.

The available prospective data (collected from approximately 40 patients) indicate that the patient's ability to have an erection was unaffected by the stent. The percentage of the patient population that retained the ability to always have an erection remained constant at 50% (from preinsertion through 12 months). The proportion of patients obtaining a "full" rather than partial erection remained at approximately 75%. No patients experienced pain on erection and few experienced mild pain during sexual activity prior to stent implantation. After UroLume™ implantation, some patients at the 6 week follow-up reported mild to moderate pain with erections or sexual activity.

The ability to ejaculate appears to be preserved. The patient's perception of the amount of ejaculate also remained generally constant. Pain with ejaculation may have improved following implantation, with 72% reporting no pain prior to implant, while 100% were pain-free at 1 year. Retrograde ejaculation was reported in six patients, however five cases were either reported preinsertion or were attributed to other causes.

O. Removals

A total of seven UroLume™ removals were needed during the study, with all but one occurring within 9 months of treatment. The removals occurred for a variety of reasons: four for reasons of pain and discomfort, one for stricture recurrence within the stent, one from urethral discharge and inflammation, and one to prevent stent displacement from urethral catheterization necessary due an atonic bladder secondary to spinal surgery. In one of the removals, the investigator tried to remove the UroLume™ without resecting the epithelium around it, causing the device to unravel. Each strand of the device needed to be removed separately.

P. Deaths

Ten patients died during the study. One patient died the day after implantation as a result of an intraventricular cerebral hemorrhage. The patient had been hospitalized for 7 weeks prior to device insertion, and had a prior history of septic embolus. One patient died at 6 weeks due to myocardial infarction. Two patients died at 4 months due to cerebral vascular accidents. Two patients died at 16 months, due to congestive heart failure and malignant fibrous histiocytoma, respectively. One patient died at 20 months due to squamous cell carcinoma of the urethra. This is the same case discussed previously. Three additional patients died more than 3 years after implantation; two were attributed to cerebral vascular accidents, and one was attributed to myocardial infarction. None of the deaths were determined to be device related.

Q. Success/Failure

To be considered a success according to the study criteria, the patient must have met each of the following three conditions: 1) the patient did not need retreatment within 12 months of insertion, 2) no removal of the UroLume™ was needed within 12 months of insertion, and 3) the patient was brought into the 95th percentile of the Liverpool Nomogram for urinary flow rate by 12 months.

All 173 patients were considered for the success criteria regarding retreatment and removal within 12 months of insertion. Urinary flow rate at 12 months was available for 128 patients. The overall success analysis (criteria 1, 2 and 3) was based on the 128 patients for whom the Liverpool Nomogram could be assessed, as well as an additional nine patients for whom flow rate was not available but were known failures due to retreatment or removal. Therefore, the analysis of success for all three criteria is based on 137 patients (Table 6). Due to the protocol deviations as noted above a success rate based on an all patients enrolled (i.e., an intent-to-treat cohort) was not calculated.

**Table 6 - Percentage of Successes and Failures**

| Success Criteria Used | Success | Failure |
|---|---|---|
| **1, 2, and 3 criteria listed above** | **67.9% (93/137)** | **32.1% (44/137)** |
| 1, 2, and 3 criteria listed above (1YC only) | 75.0% (39/52 ) | 25.0% (13/ 52) |
| 1, 2, and 3 criteria listed above (2YC only) | 79.2% (19/24 ) | 20.8% ( 5/ 24) |
| 1 Only - patients NOT needing retreatment | 86.1% (149/173) | 13.9% (24/173) |
| 2 Only - patients NOT needing removal | 96.5% (167/173) | 3.5% ( 6/173) |
| 3 Only - 95th percentile of Liverpool nomogram | 86.0% (110/128) | 14.0% (18/128) |
| 3 Only - 95th percentile of nomogram (1YC) | 85.0% ( 44/52 ) | 15.0% ( 8/ 52) |
| 3 Only - 95th percentile of nomogram (2YC) | 83.0% ( 20/24) | 17.0% ( 4/ 24) |

Of the 24 retreatment failures (13.9%) noted above, 16 of these patients required just one additional treatment. Statistical analysis indicates that stricture length affects outcome. Patients with strictures less than 2.0 cm in length had the best outcomes overall; 67% of these patients were termed successes without any reported complications, while only 9% of patients with strictures > 3.0 cm in length met this criteria.

## X. CONCLUSION DRAWN FROM THE STUDIES

The laboratory, animal, and clinical data provide reasonable assurance of the safety and effectiveness of the UroLume™ device for the treatment of recurrent benign urethral stricture disease, when used as indicated, in accordance with the label.

## XI. PANEL RECOMMENDATION

The Gastroenterology and Urology Devices Advisory Panel met to discuss the application on January 20, 1995. The Panel recommended that the application be approved pending submission to and approval by the Center for Devices and Radiological Health (CDRH) of: modifications to the labeling, plans for post-approval studies, and development of a device registry. The Panel recommended that the labeling be modified to (1) limit use to patients over 30 years of age with recurrent bulbar urethral strictures less than 3.0 cm in length; (2) emphasize that the UroLume™ is not intended for the treatment of strictures outside the bulbar urethra, or as an initial intervention for urethral strictures; (3) address the potential for adverse events which were reported; (4) explain that there is no information regarding stent removal and subsequent replacement; and (5) recommend long-term monitoring of UroLume™ patients.

The Panel also recommended that two post-approval studies be conducted. The first recommendation involved continuing follow-up of the 92 patients in the clinical trial who experienced hyperplasia to assess the long-term effects of the hyperplasia, any pathological changes, and the need for retreatment for a combined total of 10 years postinsertion. The second recommendation involved the enrollment of a new cohort of 100 patients, to be followed for 5 years, to assess the incidence of several types of adverse events which were not fully addressed by the clinical trial, including urinary tract infection, urinary incontinence, post void dribbling, hyperplasia, and stone formation. The Panel recommended that this study of 100 patients also assess sexual dysfunction at 1 year postimplantation. Finally, the Panel recommended that a registry be established to enable identification of all patients receiving the UroLume™.

## XII. CDRH DECISION

CDRH agreed with the Panel's recommendations that the PMA be approved subject to conditions, and concurred with each of the conditions recommended by the Panel except the limitation of device use to patients over 30 years of age. While CDRH agrees that insufficient data are available in this population, there is also insufficient basis to restrict its use in this group. Therefore, the labeling has been modified to add a precaution indicating that safety and effectiveness of the UroLume™ has not been demonstrated in patients under 30 years of age. In addition to the Panel's recommended conditions, CDRH also required other information, some of which reflects information discussed during the Panel's discussions but not included in the final recommendations. These additional conditions included the requirement for patient labeling, instructions concerning the placement and removal of multiple stents, the addition of labeling statements to better describe the clinical results, clarification of the training requirements, and specific elements of the post-approval study.

FDA issued a letter to American Medical Systems on February 16, 1995, advising that its PMA was approvable subject to the conditions listed above as recommended by the Panel and required by FDA. In amendments received by FDA on August 16 and October 31, 1995, American Medical Systems submitted the required information.

The company addressed the labeling issues discussed in the approvable letter. To fulfill the conditions of approval, the applicant will conduct two separate studies to address FDA's and the Panel's concerns. The first study will further assess long-term hyperplastic tissue growth inside the stent and stone formation for an additional 5 years in the remaining 144 patients currently enrolled in the study.

The second study will enroll 100 new patients followed for 2 years to assess urinary tract infection, incontinence, hyperplasia, post-void dribbling, quality of life, and to collect 1-year sexual function data. Although the Panel recommended a 5-year study, FDA and the applicant agreed that the Panel's concerns could be addressed sufficiently in a 2-year study. To satisfy the final condition of approval, the applicant will develop a method to identify the patients that receive the device.

CDRH determined that, based on the modified labeling and post-approval studies, the application was approvable without further conditions.

FDA inspections completed on March 15 and 22, 1996, determined the manufacturing facilities to be in compliance with the Good Manufacturing Practices Regulation.

CDRH issued an approval order for the application on May 6, 1996.

## XIII. REFERENCES


1. Kropp, K.A.: Stricture of the male urethra. in Gillenwater, J.Y., Grayhack, J.J., Howards, S. S. and Duckett, J.W. (Eds.): Adult and Pediatric Urology. Year Book Medical Publishers, Chicago. 1987, pp. 1297-1314.

2. Jordan, G.J. and Devine, P.C.: Management of urethral stricture disease. Urol. Clin. North America. **15:** 277-289 (1988).

3. Devine, C.J. Jr.: Surgery of the urethra. in Walsh, P.C., Gittes, R.F., Perlmutter, A.D., Stamey, T.A. (Eds.): Campbell's Urology, 5th ed. W.B. Saunders Co., Philadelphia. 1986, pp. 2853-2887.

4. Madduri, S., Kamat, M.H. and Seebode, J.J.: Urethral stricture treated with soft catheter dilation. Urology, **4:** 504-508 (1974).

5. Newmann, L.H., Stone, N.N., Chircus, J.H. and Kramer, H.C.: Recurrent urethral stricture disease managed by clean intermittent self-catheterization. J. Urol., **144:** 1142-1143 (1990).

6. Lawrence, W.T., MacDonagh, R.P., Iacovou, J., James, M.J., Bates, C.P., Bishop, M.C., Dunn, M. and Lemberger, R.J.: New treatment for urethral strictures. Lancet, Sept. **3:** 572 (1988).

7. Lawrence, W.T., and Iacovou, J.: Intermittent low friction catheterization for strictures. J. Urol., **145 supplement:** Abstract 107 (1991).

8. Devereux, M.H. and Burfield, G.D.: Prolonged follow-up of urethral stricture treated by intermittent dilatation. Br. J. Urol., **42:** 321-329 (1970).

9. Russinovich, N.A.E., Lloyd, L.K., Griggs, W.P. and Jander, H.P.: Balloon dilatation of urethral strictures. Urol. Radiol., **2:** 33-37 (1980).

10. Jamison, M.H.: Urethral stricture. in O'Reilly, P.H. (Ed.) Obstructive Uropathy. Springer Verlag, New York. 1986, pp. 313-320.

11. Haylen, B.T.: Maximum and Average Flow Rates in Normal Male and Female Populations - the Liverpool Nomograms. Brit. J. Urol., **64:** 30-38 (1989).

12. Jorgensen, J.B., Jensen, K.M.E., Bille-Brahe, N.E. and Mogensen, P.: Uroflowmetry in asymptomatic elderly males. Br. J. Urol., **58:** 390-395 (1986).

13. Romero, P.P., Mira, L.A.: Clinical and bacteriological aspects of urinary infections associated with male urethral stenosis. Rev. Clin. Esp., **188:** 281-287 (1991).

14. Bickel, A., Culkin, D.J., Wheeler, J.S. Jr.: Bladder cancer in spinal cord injury patients. J. Urol., **146:** 1240-1242 (1991).

15. Kaufman, J.M., Fam, B., Jacobs, S.C., Gabilondo, F., Yalla, S., Kane, J.P., Rossier, A.B.: Bladder cancer and squamous metaplasia in spinal cord injury patients. J. of Urology, **118:** 967-971 (1977).

16. Sawczuk, I., Acosta, R., Grant, D., De Vere White, R.: Post Urethroplasty Squamous Cell Carcinoma. New York State Journal of Medicine, **May 1986:** 261-263.

17. Colapinto, V., Evans, D.H.: Primary Carcinoma of the Male Urethra Developing After Urethroplasty for Stricture. J. Urol., **118:** 581-584 (1977).

18. Broecker B.H., Klein, F.A., Hackler, R.H.: Cancer of the bladder in spinal cord injury patients. J. Urol. **125:** 196-197 (1981).

19. Ashken, M.H., Coulange, C., Milroy, E.J.G., Sarramon, J.P.: European experience with the urethral wallstent for urethral strictures. Eur. Urol., **19:** 181-185 (1991).

## XIV. APPROVAL SPECIFICATIONS

Directions for use: See labeling.

Hazards to Health from Use of the Device: see indications, contraindications, warnings, precautions and adverse events in the labeling.

Post-approval Requirements and Restrictions: see approval order.

Labeling

Labeling

**Errata Sheet**
**UroLume™ Endoprosthesis for Recurrent Bulbar Urethral Strictures**
**Instructions For Use brochure**

**Page 3:**

1. Warning #9 should read 'Encrustation of the prosthesis may occur on wires that do not become covered by epithelium. If encrustation develops which causes obstruction, or is associated with repeated infection or intermittent hematuria, it should be removed using electrohydraulic lithotripsy."

2. Precaution #5 should read 'Squamous cell carcinoma may be an underlying cause of unexplained urethral stricture disease. Patients should be carefully evaluated prior to use of this device.

**Page 4:**

1. Add the following section after precaution #14:
**Adverse Events**

Adverse events noted throughout the study included: post-void dribbling (88%), pain (71%), incontinence (57%), hyperplasia/narrowing (53%), hematuria (44%), positive urine culture (41%), new stricture (32%), erection pain (27%), sexual activity pain (14%), additional insertion procedures (11%), ejaculation pain (9%), pads used for incontinence (8%), resection (8%), catheterization (8%), deaths unrelated to device (6%), retention (5%), migration (5%), urine leak with ejaculation (5%), decreasing stream (4%), dilation within stent area (3%), retrograde ejaculation (3%), hematospermia (3%), white ring of tissue at the end of the stented region (3%), erection ability change from full to partial (3%), squamous metaplasia (3%), encrustation related to stent (3%). Other complications/side effects noted in 2% or less of the patient population include self intermittent catheterization inside stent area, polyps on urethral wall, pooling of urine, testicular pain, drug therapy used for incontinence, itching, thinner semen, blood following ejaculation, odor in urine, curvature of penis, sphincter impaired by stent, superficial abrasion to anterior urethra during stent removal, urinary stream spraying, erection time shortened, stent end did not expand, wires broken during repositioning, bloody discharge while walking, wire ends protruding into lumen, difficulty emptying bladder, progressively worsening erections, inflammation of urethral tissue, urgency, clot retention, medication given for urethral discomfort, soreness noted after ejaculation, urination only while sitting, irregular lumen in distal urethra, stent minimally elevated from mucosa circumferentially, bleeding due to exposed stent with febrility of mucosa, delayed ejaculation with intercourse, odor in semen, gap between stents, pressure in scrotum with erections, stent wire exposed, exercises for incontinence, excessive mucosa, erectile dysfunction, bulbous edema, proliferative changes at ends of stent and narrowing of urethra.

No deaths during the clinical study were attributed to device use. Refer to the Clinical Results section for further information about the adverse events.

2. Change "**Clinical Results and Adverse Events**" to "**Clinical Results**"

3. Change first paragraph in second column to read 'In clinical studies 86% (149/173) of patients were considered retreatment successes (no further treatments were required for treatment of the urethral stricture within the first twelve months following insertion). A total of 97% (167/173) of the patients were considered successes based upon the device not requiring removal within the first twelve months following insertion. When evaluating success based upon improvement in urinary flow rate, 86% (110/128) of the patients were considered a success (success defined as the patients being brought into the 95th percentile of their age adjusted peak flow range as defined by the Liverpool Nomograms[1] at twelve months following insertion). Using a combined measure of success including devices did not require removal within the first twelve months following insertion, no further treatments were required for treatment of the urethral stricture within the first twelve months following insertion, and the patient was brought into the 95th percentile of their age adjusted peak flow range (as indicated by the Liverpool nomogram[1] ) at twelve months following insertion, 68% (93/137) of patients were considered to be successes.

**Page 5:**

1. The last sentence of paragraph 5 should read "The patient died of squamous cell carcinoma".

**Page 6:**

1. The third paragraph should read "Hyperplasia was noted in 40% of the patients...".

**Page 9:**

1. In the front security button description, "urologist" should read "physician".

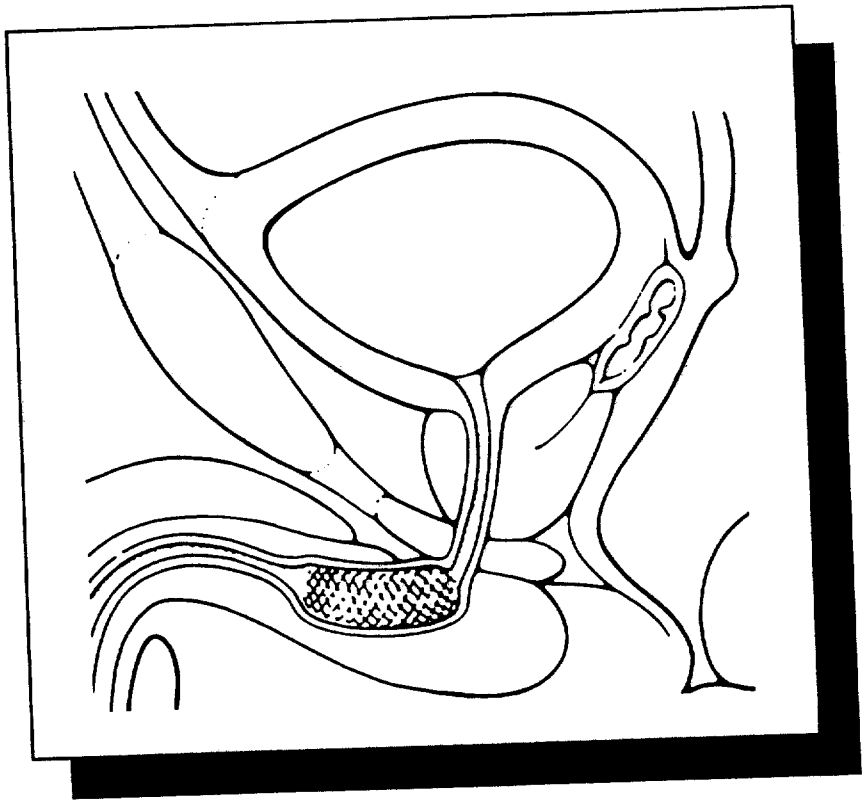
**Page 11**:

1. Revise the first paragraph of **Patient Communication** to read "To prepare a patient to make an informed decision regarding implantation of the UroLume prosthesis, the physician should communicate several items to the patient and provide a Patient Information Brochure to each patient.



30

# UroLume™
*Endoprosthesis*



***For Recurrent Bulbar Urethral Stricture***

**Instructions For Use**

Pfizer

American Medical Systems

31

## Contents

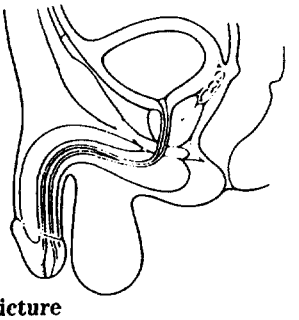
## Device Description

The UroLume™ Endoprosthesis is a braided mesh cylinder made of high strength, implant grade, superalloy wire. The braided mesh is designed to expand radially after deployment to hold open sections of the urethra that obstruct the flow of urine. The self-expanding properties of the mesh press it against the wall of the urethra with radial force, helping to prevent migration of the prosthesis and allowing the epithelium to cover the wire mesh. The UroLume prosthesis is provided preloaded in a sterile, disposable delivery instrument. This instrument serves three purposes: 1) it constrains the prosthesis to a diameter small enough to allow it to be inserted into the urethra; 2) it permits direct visualization of the prosthesis throughout the implant procedure; and 3) it permits the physician to deploy the prosthesis accurately in the urethra.

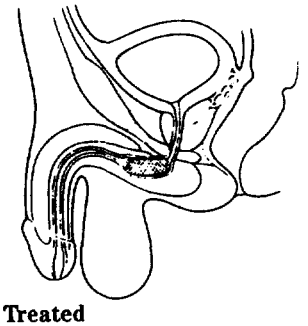
## Indications For Use

The UroLume prosthesis is intended for use in men to relieve urinary obstruction secondary to recurrent benign bulbar urethral strictures less than 3.0cm in length located distal to the external sphincter and proximal to the bulbar scrotal junction (Figure 1).

The UroLume prosthesis is not intended as an initial treatment for bulbar urethral strictures nor for the treatment of strictures outside the bulbar urethra. The UroLume prosthesis is an alternative treatment for the patient in whom previous treatment methods (dilation, urethrotomy or urethroplasty) have been unsuccessful (i.e., treatment was not effective initially in relieving stricture disease or there has been recurrence of stricture formation necessitating further treatment).



**Bulbar Stricture**



**Stricture Treated**

**Figure 1: The UroLume prosthesis holds open the portion of the bulbar urethra obstructed by urethral stricture.**

## Contraindications

The following conditions contraindicate use of the UroLume prosthesis for the treatment of urethral strictures:

1. Meatal or urethral strictures which cannot be opened to 26Fr by dilation, urethrotomy or meatotomy.
2. Strictures involving the external sphincter.
3. Patients with an active urinary tract infection.
4. Patients with other urethral conditions requiring transurethral manipulations within one month of UroLume prosthesis placement.
5. Infected, suppurating strictures.
6. Presence of a fistula at the proposed prosthesis location.
7. Patients with urethral squamous cell carcinoma.
8. Patients with a perineal urethrostomy.

## Warnin

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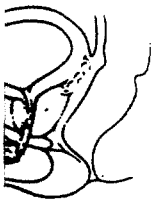

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**quamous cell carcinoma.**

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## Warnings

1. The prosthesis should not be used in patients in whom bleeding may seriously impede the visualization process. If bleeding impairs visualization, a catheter may be placed for 15 - 20 minutes until bleeding slows, allowing adequate visualization. Alternately, a catheter may be placed and the patient may return in 4 - 6 days for UroLume prosthesis placement.
2. The prosthesis should not be used in patients with bladder stones, urethral lesions distal to the bulbar-scrotal junction, or strictures caused by traumatic rupture.
3. Patients should be advised to expect mild discomfort, post void dribbling, hematuria, urgency or nocturia during the first few weeks after prosthesis placement. In most cases, these symptoms resolve or diminish spontaneously.
4. Prior to utilizing the UroLume prosthesis in patients who suffer from thrombocytopenia or hemophilia and/or patients who have received blood products for the treatment of a bleeding disorder, other alternative treatment options that would put the patient at less risk of bleeding than that associated with the UroLume prosthesis should be considered.
5. Ensure that the prosthesis does not extend into the external sphincter. Placing the prosthesis in the external sphincter may cause the patient to be incontinent.
6. Infection could occur at the prosthesis site. Infection may be treated using bactericidal antibiotic therapy or device removal.
7. Longitudinal compression of the prosthesis by instrumentation could cause trauma to the urethra or could dislodge the prosthesis. Transurethral instrumentation should be avoided prior to epithelial ingrowth.
8. The prosthesis may migrate and/or shorten resulting in incomplete coverage of the stricture. If this occurs, additional prostheses may be placed or the prosthesis position may be adjusted to assure complete stricture coverage.
9. Encrustation of the prosthesis may occur on wires that do not become covered by epithelium If encrustation develops which causes obstruction, or is associated with repeated infection or intermittent hematuria, they should be removed using electrohydraulic lithotripsy.
10. Hyperplastic ingrowth may obstruct the passage of urine. If obstruction occurs, hyperplastic ingrowth may be removed using resection, dilation or fulguration or an additional prosthesis may be placed.
11. Removal of the prosthesis for any reason after epithelial ingrowth could result in significant trauma to the urethra. After epithelial tissue has grown over the prosthesis, it must be resected before the prosthesis is removed or the prosthesis may unravel.

## Precautions

1. The UroLume prosthesis kit (prosthesis, delivery instrument, telescope stabilizer, ACMI adaptor ring) is provided sterile. Do not resterilize any components. Resterilization causes damage to the components and reuse may cause trauma to the urethra.
2. This device is to be used only by physicians who have received appropriate training regarding the use of the UroLume prosthesis. Each physician should view an instructional video prior to attempting a UroLume prosthesis insertion.
3. Limited data are available for patients younger than 30 years of age, therefore, safety and effectiveness of the UroLume prosthesis in this population has not been fully established.
4. The prosthesis should not be used for the treatment of strictures longer than 3cm. Safety and effectiveness of the device in strictures longer than 3cm has not been fully established.
5. Squamous cell carcinoma may be an underlying cause of unexplained urethral stricture disease, therefore additional work up may be necessary.

6. The long term safety and effectiveness of the UroLume prosthesis has not been demonstrated, therefore continuing follow-up is recommended.
7. Safety and effectiveness of prosthesis removal and subsequent replacement has not been established.
8. Verify that the prosthesis extends beyond the stricture by at least 5mm at each end.
9. Failure to resheathe the prosthesis before advancing the delivery instrument will result in compression of the prosthesis and possible trauma to the urethra.
10. Passing a cystoscope through the prosthesis may displace the prosthesis.
11. Exercise care with instrumentation to ensure that the first prosthesis is not dislodged while placing a second prosthesis.
12. Use care to avoid contact that would displace the prosthesis or modify its position. Do not use a urethral catheter until the prosthesis is stabilized by epithelial ingrowth. Inserting a catheter into the urethra before epithelium has grown over the prosthesis may cause the prosthesis to move out of position and may cause trauma to the urethra.
13. Use care in handling the explanted prosthesis to prevent the prosthesis from puncturing the protective surgical gloves.
14. Do not attempt to remount the prosthesis onto the delivery instrument. Attempting to insert a remounted prosthesis into the urethra can cause the delivery instrument to function incorrectly and cause trauma to the urethra.

## Clinical Results and Adverse Events

In clinical studies, 86% of patients were considered retreatment successes (no further treatments were required for treatment of the urethral stricture within the first twelve months following insertion). A total of 97% of the patients were considered successes based upon the device not requiring removal within the first twelve months following insertion. When evaluating success based upon improvement in urinary flow rate, 86% of the patients were considered a success (success defined as the patients being brought into the 95th percentile of their age adjusted peak flow range as defined by the Liverpool Nomograms[1] at twelve months following insertion). Using a combined measure of success including: devices did not require removal within the first twelve months following insertion, no further treatments were required for treatment of the urethral stricture within the first twelve months following insertion, and the patient was brought into the 95th percentile of their age adjusted peak flow range (as indicated by the Liverpool nomogram[1]) at twelve months following insertion, 68% of patients were considered to be successes.

Conditions which have required removal of the device in 7 patients include discomfort, stent migration, restricturing, urethral discharge/ inflammation and urethral catheterization required due to an unrelated surgical procedure prior to epithelialization. Additional reasons for removal may be indicated if additional data becomes available.

A total of 173 patients (mean age 52 years) have been studied in the U.S. and Canada. Outcome effectiveness variables identified in these patients included peak urinary flow rate and total symptom score. (Total symptom score was determined by scoring 10 individual symptoms: hesitancy, poor flow, incomplete emptying, frequency, nocturia, painful urination, hematuria, two stage voiding, post void dribbling and prolonged voiding time). Total symptom score could range from 0 (no symptoms) to 30 (all marked severity symptoms).

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Mean peak urinary flow rate prior to insertion was 9.8cc/sec in 149 patients with available data. Six weeks following insertion, mean peak flow rate was 24.4cc/sec in 150 patients with available data. The mean peak urinary flow rate more than doubled following insertion of the UroLume prosthesis. One year following insertion, mean peak flow rate was 22.7cc/sec in 128 patients with available data. Evaluation of clinical data indicated a significant increase in both peak and average flow results for the majority of patients following UroLume prosthesis insertion. Substantial improvements in flow rates were maintained throughout the study. Six weeks following insertion, 90% of the patients with peak flow data (135 out of 150 patients) met the 95th percentile of the age adjusted flow range defined by the Liverpool Nomogram. One year after insertion, 86% (110 out of 128 patients) were brought into the 95th percentile.

Mean total symptom score prior to insertion was 12.7 in 157 patients with available data. Six weeks following insertion, mean total symptom score had improved to 3.6 in 161 patients with available data. One year following insertion, the mean total symptom score was still significantly improved at 2.2 in 140 patients with available data.

The rate of retreatment in the years following UroLume prosthesis insertion was dramatically reduced from that experienced in the years preceding UroLume prosthesis insertion. In the one year period before UroLume prosthesis insertion, 74.5% of 106 patients required treatment for their urethral stricture. In contrast, only 12.3% of these same patients required treatment for their urethral stricture in the year following UroLume prosthesis insertion. These results may change as further data becomes available.

During clinical evaluation, most patients demonstrated complete (90-100%) epithelialization by six months following stent insertion. Patients whose devices did not become completely covered were found to have no apparent increased propensity for urinary tract infection, stent migration, encrustation or other complications. These patients experienced similarly substantial relief of obstructive symptoms as those patients whose devices became completely covered in epithelial tissue. Many of the complications/side effects noted throughout the study were also noted by patients prior to insertion of the UroLume prosthesis.

There were 10 reported deaths during the clinical evaluation. No deaths were indicated to be related to the device. Causes of the deaths include: intraventricular cerebral hemorrhage possibly secondary to mycotic aneurysm, myocardial infarction (2 patients), cerebral vascular accident (4 patients), congestive heart failure, malignant fibrous histiocytoma and urethral squamous cell carcinoma. Abnormal tissue (cauliflower appearance) was noted within the urethra of one patient before UroLume prosthesis insertion. The prosthesis was removed nine months after insertion. He died of squamous cell carcinoma 20 months after insertion.

Squamous metaplasia was identified in five patients throughout the clinical study. Four of these five patients previously underwent skin graft urethroplasty. As such, squamous cells would be anticipated in these patients. The remaining patient was the patient who was also diagnosed with squamous cell carcinoma.

Pain/discomfort was noted by 40% of the patients at pre-evaluation (25% mild, 11% moderate and 4% marked). Up to six weeks following insertion, 61% of the patients noted some degree of pain/discomfort (40% mild, 15% moderate and 6% severe). Six months after insertion of the UroLume prosthesis, the incidence of pain/discomfort had dropped to 28.6% of the patients (21.3% mild and 7.3% moderate). One year after insertion, 18% of patients reported some pain/discomfort (14% mild, 2% moderate and 2% severe). Only 3 patients had their devices removed due to pain/discomfort throughout the duration of this study.

Incontinence was experienced by 40% of the patients six weeks after insertion (26% mild, 10% moderate and 4% marked). Six months after insertion, 33% of patients noted some incontinence (24% mild, 6% moderate and 3% marked). After one year, 28% of the patients were experiencing some incontinence (19% mild, 8% moderate and

1% marked in severity). No devices were removed due to incontinence during this study. These results may change as additional data becomes available.

Post void dribbling was noted by 66% of the patients at pre-insertion (31% mild, 21% moderate and 14% marked in severity). Six weeks after insertion, 81% of the patients were experiencing post void dribbling (52% mild, 21% moderate and 8% severe). Six months after the UroLume prosthesis insertion, 61% of patients experienced post void dribbling (48% mild, 10% moderate and 3% marked in severity). Post void dribbling was noted in 54% of patients one year after insertion (41% were mild, 10% moderate and 3% marked in severity). No devices were removed due to post void dribbling during this study.

Hyperplasia was noted by 40% of the patients six months after insertion (32% mild, 8% moderate in severity). One year following insertion, 33.8% of the patients were experiencing hyperplasia (24.3% mild, 8.1% moderate and 1.4% marked in severity). Eighty-four percent of the patients who experienced hyperplasia required no treatment. One device was removed due to hyperplasia during this study.

Positive urine cultures were noted by 9% of patients at pre-insertion. Six weeks following insertion, 7% of the patients had a positive urine culture. Six months after the insertion procedure, 11% of the patients reported a positive urine culture. One year following insertion, 21% of the patients reported a positive urine culture. The incidence of positive urine culture was reduced two years following insertion, such that 12% of the patients reported a positive urine culture. Forty-eight percent of the patients in this study were noted to have a history of positive urine cultures. No devices were removed due to positive urine cultures during this study.

New strictures were identified proximal to the location of the UroLume prosthesis in 23 patients. New strictures distal to the location of the UroLume prosthesis were noted in 24 patients. New strictures were noted both proximal and distal to the location of the UroLume prosthesis in 9 patients. Eleven patients required treatment for a new stricture.

Hematuria was experienced by 11% of the patients prior to insertion (8% were mild, 1% were moderate and 2% were marked in severity). Up to six weeks following insertion, 31% of patients were experiencing hematuria (27% mild and 4% moderate). Six months following insertion, 12.1% of patients experienced hematuria (10.7% were mild, 0.7% were moderate and 0.7% were marked). One year following insertion, 9% were experiencing hematuria (7% mild and 2% moderate).

An increase in pain with erections was noted after stent insertion which appears to subside or diminish over time. Erection pain was noted in 64% of patients up to six weeks following insertion (39% mild, 14% moderate and 11% severe). At six months following insertion, only 19% of the patients noted erection pain (14% mild and 5% moderate in severity). Twelve months following insertion, 14% of patients were experiencing erection pain, all mild in severity. No change was noted in ejaculation ability following insertion. In patients with pre-insertion data, reports of pain during ejaculation decreased after stent insertion. Sexual function effects may change if further data becomes available.

Additional insertion procedures were required by 11% of the patients involved in this study. Nine percent required two insertion procedures and 2% underwent three insertion procedures.

There were five reported incidents of stone formation in connection with the prosthesis, three requiring treatment to remove the stones. One patient had granulation noted within the stent at two years post-insertion. One patient had tiny stones apparent in the stent which were flushed away during cystoscopy. Of the three patients requiring removal, one patient was reported at one year to have a small calculi removed without difficulty. One other patient had stones adhered to the exposed wires of the stent three years following insertion. The stones were crushed and removed with grasping forceps without difficulty. The stent completely epithelialized after the stones were removed. The third patient had stones adhered to the urethral mucosa 18 months after stent insertion. The stent wires were completely covered with

epithelium. The stones were removed using a basket extractor. A bladder stone was also removed from this patient 3.5 years after insertion. This patient had a pre-insertion history of bladder calculi formation.

Other complications/side effects noted throughout the study included: ejaculation pain (8%), pads used for incontinence (8%), resection (8%), catheterization (8%), sexual activity pain (7%), retention (5%), migration (5%), urine leak with ejaculation (5%), decreasing stream (4%), dilation within stent area (3%), retrograde ejaculation (3%), hematospermia (3%), white ring of tissue at the end of the stented region (3%), and erection ability change from full to partial (3%). Other complications/ side effects noted in 2% or less of the patient population include: self intermittent catheterization inside stent area, polyps on urethral wall, pooling of urine, testicular pain, drug therapy used for incontinence, itching, thinner semen, blood following ejaculation, odor in urine, curvature of penis, sphincter impaired by stent, superficial abrasion to anterior urethra during stent removal, urinary stream spraying, erection time shortened, stent end did not expand, wires broken during repositioning, bloody discharge while walking, wire ends protruding into lumen, difficulty emptying bladder, progressively worsening erections, inflammation of urethral tissue, UTI requiring hospitalization, necrotic tissue, urgency, clot retention, medication given for urethral discomfort, soreness noted after ejaculation, urination only while sitting, irregular lumen in distal urethra, stent minimally elevated from mucosa circumferentially, bleeding due to exposed stent with febrility of mucosa, delayed ejaculation with intercourse, odor in semen, gap between stents, pressure in scrotum with erections, stent wire exposed, exercises for incontinence, excessive mucosa, erectile dysfunction, bulbous edema, proliferative changes at ends of stent and narrowing of urethra.

# Detailed Description

## The Prosthesis

The UroLume Endoprosthesis is a braided mesh cylinder made of high strength, implant grade, superalloy wire. The braided mesh is designed to expand radially after deployment to hold open sections of the urethra that obstruct the flow of urine.

For use in the bulbar urethra, the UroLume prosthesis is available in the following sizes:

Reference lengths: 2.0cm, 2.5cm, and 3.0cm

Reference diameter: 14mm

The self expanding properties of the mesh press it against the wall of the urethra with radial force, helping to prevent migration of the prosthesis and allowing the epithelium to cover the wire mesh.

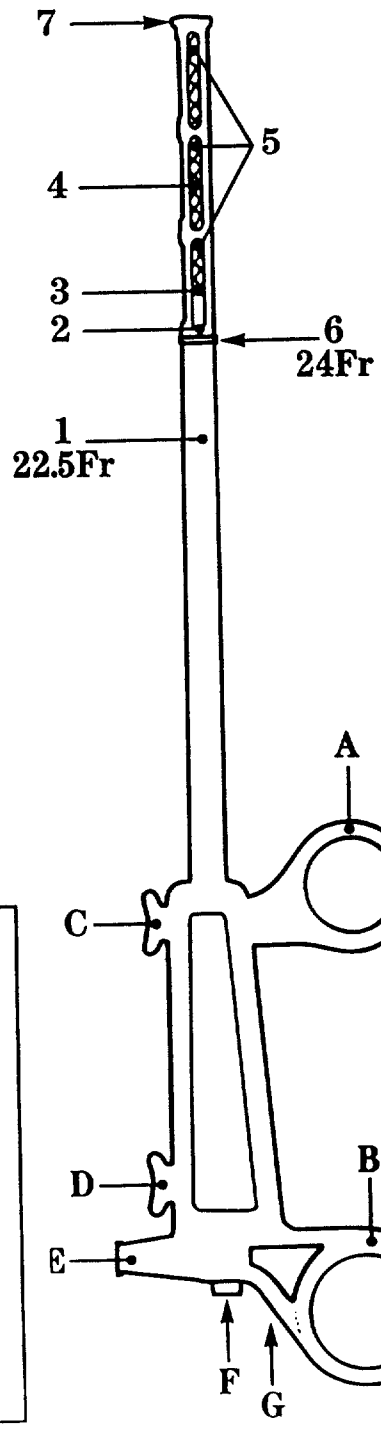
## The Disposable Delivery System

The UroLume prosthesis is provided preloaded in a sterile, disposable delivery instrument. This instrument serves three purposes: 1) it constrains the prosthesis to a diameter small enough to allow it to be inserted into the urethra; 2) it permits direct visualization of the prosthesis throughout the implant procedure; and 3) it permits the physician to deploy the prosthesis accurately in the urethra. Each part of the delivery instrument is described in Figure 2.

**Figure 2: The UroLume prosthesis is preloaded in a disposable delivery instrument.**

1. Outer Shaft
2. Retractable sheath (intermediate shaft)
3. Inner shaft and holding mechanism
4. Prosthesis
5. Windows
6. Rounded collar
7. End ring

A. Front finger grip
B. Rear finger grip
C. Front security button
D. Rear security button
E. Water irrigation port
F. Telescope port
G. Telescope stabilizer port



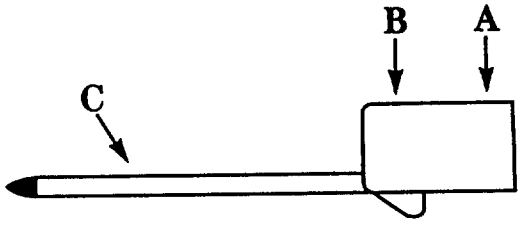




**Figure 2a: The telescope stabilizer facilitates telescope movement within the delivery instrument, while preventing telescope rotation.**

A. Storz/Wolf/ACMI telescope lock
B. Olympus telescope lock
C. Stabilizing pin

The forward end of the delivery instrument has the following features (Figure 2):

1. *Outer Shaft*
   The outer shaft stabilizes the instrument during deployment of the prosthesis.
2. *Retractable Sheath (Intermediate Shaft)*
   By manipulating the finger grips, the physician is able to draw back and advance the retractable sheath to alternately expose and cover the prosthesis until the optimum position for deployment of the prosthesis is found.
3. *Inner Shaft and Prosthesis Holding Mechanism*
   The inner shaft has an open lumen which accommodates a 12Fr telescope. At the tip of the inner shaft is a holding mechanism which holds the prosthesis in the delivery instrument until it is released.
4. *Prosthesis*
   Each delivery instrument is preloaded with a prosthesis. Preloaded in the delivery instrument, the prosthesis assumes a compressed and elongated form. When the prosthesis is released from the delivery instrument, it spontaneously expands from its constrained shape. Unconstrained, the prosthesis assumes a shorter length and larger diameter form.
5. *Windows*
   Window openings in the retractable sheath permit endoscopic visualization of the urethra and the prosthesis throughout the placement procedure.
6. *Rounded Collar*
   The rounded collar at the end of the outer shaft eases insertion into the urethra.
7. *End Ring*
   The end ring at the end of the delivery instrument eases insertion into the urethra.

The handle end of the delivery instrument has the following features (Figure 2):

A. *Front Finger Grip*
   The front finger grip has two functions: 1) Pulling the front finger grip towards the rear finger grip causes the retractable sheath to draw back, exposing the prosthesis. 2) Pushing the front finger grip away from the rear finger grip causes the retractable sheath to slide forward, covering the prosthesis.

B. *Rear Finger Grip*
   The rear finger grip is stationary. It is used to stabilize the delivery instrument during prosthesis deployment.

C. *Front Security Button*
   The front security button enables the urologist to partially deploy the prosthesis, without releasing it from the delivery instrument. As the prosthesis is uncovered, it partially opens, but does not release.

D. *Rear Security Button*
   Pressing down on the rear security button permits release of the prosthesis. Once the rear security button is pressed, the prosthesis must be released.

E. *Water Irrigation Port*
   The delivery instrument's irrigation port, with its luer lock, permits a constant washing of the urethra and telescope.

F. *Telescope Port*
   The telescope port accommodates a 12Fr telescope. The telescope can be moved in and out to view the implant procedure through the windows and at the delivery instrument tip.

G. *Telescope Stabilizer Port*
   The telescope stabilizer port accommodates the telescope stabilizer (Figure 2a) provided with the UroLume prosthesis. The telescope stabilizer has three functions: 1) It enables the delivery instrument to accommodate the major telescopes. The 30cm Storz, Wolf and ACMI (M-2) telescopes can be positioned in lock A, and the 28cm Olympus telescope can be positioned in lock B. 2) It stabilizes the telescope on the delivery instrument, preventing rotation and keeping the light source upright. 3) It enables the telescope to slide freely within the delivery instrument.

   An ACMI adaptor ring is provided for use with the ACMI telescope. The ACMI adaptor ring enables the ACMI telescope to be positioned into lock A of the telescope stabilizer.

## Components

The UroLume prosthesis is provided in a kit including the components needed to place one prosthesis in the bulbar urethra. All components are sterile. UroLume prosthesis kits contain the following items:

- one (1) UroLume prosthesis (2.0cm, 2.5cm, or 3.0cm)
- one (1) disposable delivery instrument
- one (1) telescope stabilizer
- one (1) ACMI adaptor ring

***Caution: All UroLume prosthesis kits are provided sterile. Do not resterilize any components. Resterilization causes damage to the components, and reuse may cause trauma to the urethra.***

### Prosthesis Specifications

*Diameter*

| | |
|---|---|
| Compressed diameter | 6mm |
| Reference diameter | 14mm |

*Product Number*

| | |
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| For 2.0cm prosthesis | 72402010 |
| For 2.5cm prosthesis | 72402011 |
| For 3.0cm prosthesis | 72402012 |

### Delivery Instrument Specifications

*Diameter*

| | |
|---|---|
| Retractable sheath | 21.0 Fr |
| Inner lumen | 12.0 Fr |
| End ring | 24.0 Fr |

*Useable Shaft Length*

| | |
|---|---|
| For 2.0cm prosthesis | 20.7cm |
| For 2.5cm prosthesis | 19.5cm |
| For 3.0cm prosthesis | 18.5cm |

**UroLume Delivery Instrument / Telescope Compatibility**

| Telescope Model | | Prosthesis Size | | |
|---|---|---|---|---|
| | | 2.0cm | 2.5cm | 3.0cm |
| Olympus 28cm | Compatible | YES | YES | YES |
| | Stabilizer Position | B | B | B |
| ACMI Storz Wolf 30cm | Compatible | YES | YES | YES |
| | Stabilizer Postion | A | A | A |

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## Instructions For Use

***Caution: This device is to be used only by physicians who have received appropriate training regarding the use of the UroLume prosthesis. Physicians should view an instructional video, which demonstrates insertion and removal, prior to attempting a UroLume prosthesis insertion.***

### Patient Communication

To prepare a patient to make an informed decision regarding implantation of the UroLume prosthesis, the physician should communicate several items to the patient.

1. The patient should be advised that post void dribbling may be experienced in the weeks following UroLume prosthesis insertion. Methods for managing post void dribbling should be discussed with the patient.
2. The patient should be informed that hematuria and/or pain may be experienced in the weeks following insertion.
3. Patients should be advised not to attempt any manipulation of the stent (applying unnecessary pressure to the area of the prosthesis). Manipulation of the stent can cause the stent to migrate and can cause pain.
4. Patients should be advised that transurethral catheterization or other transurethral procedures should not be used in the weeks following UroLume prosthesis insertion, until epithelialization of the UroLume prosthesis has occurred. In emergency situations, suprapubic urinary catheterization may be used, however, no transurethral instruments should be used until a physician familiar with the UroLume prosthesis can check its stability.
5. Patients should be advised to abstain from sexual intercourse and sexual activities for at least four weeks following insertion of the UroLume prosthesis.
6. Patients should be advised that bleeding may occur during the insertion procedure which would necessitate catheterization, and possible hospitalization. The patient would then need to return for stent placement.
7. Patients should be advised that occasionally there may be an unrecognized infection present at insertion.
8. Patients should be advised that there may be situations where a suprapubic tap for urinary drainage proximal to the stent would be advised.
9. Patients should be informed of actions to take in case of an emergency, i.e., when to consult a physician following insertion of the UroLume prosthesis.
10. Patients should be informed of the importance of always carrying their Medical Information Card.

### Pre-operative Set-up

*Materials*

The following materials are required for the placement procedure:

- Urethral sounds or filiform followers
- Urethrotomy equipment
- 12Fr, 0° to 12° telescope
- Water flushing set-up; typically 1 to 5 liters of sterile water on I.V. pole, 5mm tubing
- 17Fr or 21Fr cystoscope
- AMS Urethral Measuring Catheter, or a graduated ureteric catheter
- UroLume Endoprosthesis kits (two of each size recommended)

***Note:*** *A selection of at least two UroLume prosthesis kits in each size is advised. This inventory ensures that the correct size is available when the stricture is measured.*

*Premedication*
Prior to implantation with the UroLume prosthesis, patients should be given prophylactic broad-spectrum antibiotic coverage according to the protocols commonly used by the hospital.

*Patient Preparation*
Place the patient in the lithotomy position, prep with aseptic solution and drape.

*Anesthesia*
Clinical investigators found that the anesthesia required for urethrotomy or dilation is generally sufficient for prosthesis placement.

## Preparation for Prosthesis Placement

1. Perform a diagnostic cystourethroscopy.

   **Note:** *If it is not possible to pass a cystoscope through the strictured portion of the urethra, dilate, or perform urethrotomy to allow the instrument to pass.*

2. Measure the length of the stricture. To determine the length of the stricture, apply the same principles used for determining the extent of a substitution procedure. The normal urethra appears pink with normal mucosal tissue and a normal vascular pattern. When it is opened, the vascular spongy tissue is seen through its immediately overlying translucent uro-epithelial cover. A strictured area in the urethra is grey, noting pale mucosa, an irregularity in the mucosal wall and intrusiveness into the urethral lumen. It is essential to stent the entire spongiofibrosis region (grey area) to decrease the occurrence of restricturing proximal and distal to the narrowed region within the urethra as shown in Figure 3 below.

   Measure the stricture length using an AMS Urethral Measuring Catheter, following the instructions included with that product, or a graduated ureteric catheter. Instructions for measuring the urethra with a graduated ureteric catheter are as follows: Place the graduated ureteric catheter alongside the telescope into the bladder. Hold the catheter firmly and gently withdraw the telescope while counting the centimeter markings on the catheter to determine the length of the strictured area.

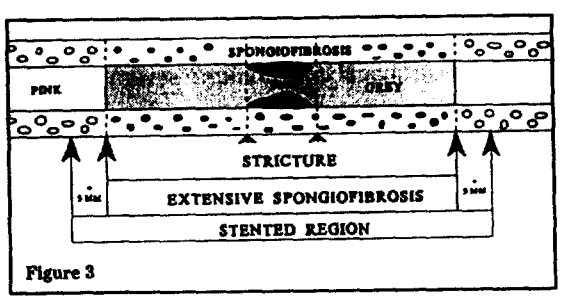

Figure 3

3. Select a prosthesis that is **1.0cm** longer than the measured length of the stricture.
4. Open the selected prosthesis package. Peel open the plastic tray and remove the sterile contents. Inspect the delivery instrument carefully, checking that the prosthesis is visible in the windows.

   ***Note:*** *No wire filaments should protrude either from the rounded collar of the delivery instrument or through the windows of the retractable shaft. Should filaments be seen protruding from the delivery instrument, return the entire system to your AMS representative and use a new UroLume prosthesis.*

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Prepare the selected UroLume deployment system for the procedure as follows:

- Attach the light source to the telescope.
- Attach the water source to the irrigation port on the delivery instrument with the water bag approximately 1 meter above the patient. If desired, a three-way tap may be connected to the luer lock of the irrigation port before attaching the water source.

  *Note: A three-way tap will reduce the cross-section of the irrigation port and, therefore, the water flow will also be reduced.*

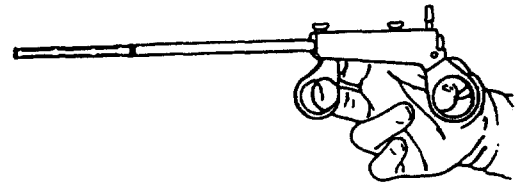
- Insert the 0 degree telescope into the telescope stabilizer and then place into the delivery instrument. During the placement procedure, the position of the prosthesis can be monitored by sliding the telescope back and forth in the delivery instrument.
- Apply a small amount of sterile lubricant over the retractable sheath to facilitate passage into the urethra.

With these preparatory steps completed, the physician is ready to proceed with the five step placement procedure (Figure 5). During the procedure, the delivery instrument may be manipulated with one hand (Figure 4), while the other hand stabilizes the penis.

**Figure 4: The front finger grip draws back the sheath to expose the prosthesis, while the rear security button prevents its inadvertent release. Reference "Placement Procedure" for complete placement instructions.**

**Insertion**

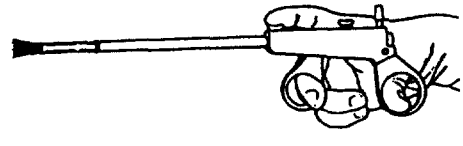
Both security buttons are in the locked position; finger grips are immobile. Hold the grips with thumb and middle finger.



**Partial Deployment**

1) Press the front security button down with the index finger.

2) Using the middle finger, pull the front finger grip back to retract the sheath.

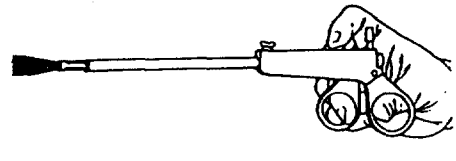


**Release**

1) Using the index finger press, then release, the rear security button.

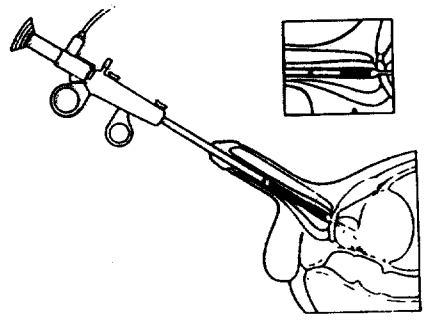
2) Using the middle finger, pull the front finger grip back.

3) Gently pull back on the delivery instrument to distance it from the prosthesis.

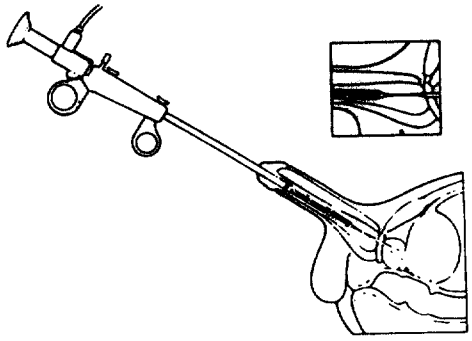


## Overview

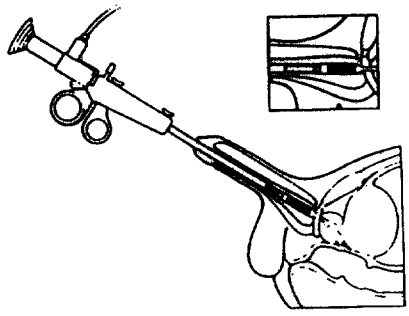
**Figure 5: Placing the UroLume prosthesis requires five procedural steps: insertion, confirmation, partial deployment, release and withdrawal.**



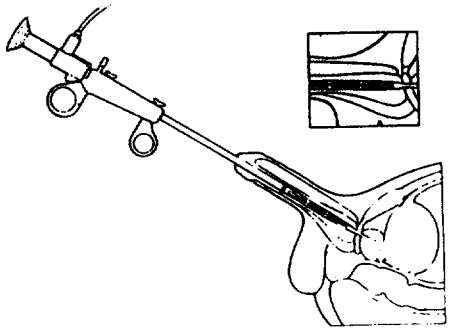
**3. Partial deployment**



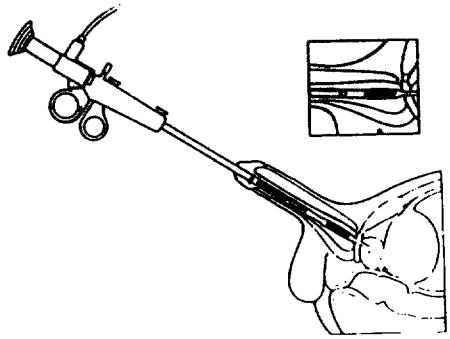
**1. Insertion**



**4. Release**



**2. Confirmation**



**5. Withdrawal**

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## Placement Procedure

1. *Insertion*

   Open the stricture using dilation and/or urethrotomy. (One incision at the 12 o'clock position or 2 incisions at 4 and 8 o'clock positions recommended. If incisions made at 4 and 8 o'clock, use care not to carry incision beyond the area of fibrosis in the spongiosum tissue to avoid extending the incision to the corpus cavernosum, which may result in shunting of blood and impotence.) The stricture must be opened to a minimum of 26Fr prior to placement of the prosthesis. This allows the UroLume prosthesis to assume the maximum diameter the urethra will allow.

   Introduce the delivery instrument into the urethra, advancing it gently under direct vision. Hold the delivery instrument stable and manipulate the telescope in and out to assess landmarks for prosthesis placement.

2. *Position Confirmation*

   Position the delivery instrument so that its rounded collar is approximately 5mm proximal to the stricture.

   If the stricture is close to the external sphincter, it may be necessary to position the prosthesis by inserting the delivery instrument through the external sphincter and then withdrawing it so that the rounded collar rests just inside the sphincter. Although it may be useful to initiate deployment within the sphincter, use care not to release the prosthesis in the external sphincter. After release, the prosthesis should be distal to the external sphincter. It should be placed in such a way that it will not impinge on the external sphincter.

3. *Partial Deployment*

   When the rounded collar of the delivery instrument is positioned appropriately proximal to the stricture, depress the front security button. This unlocks the sliding mechanism and permits the retractable sheath to slide back, exposing, but not releasing, the prosthesis. It is not necessary to continue to hold down the security button.

   Keep the back finger grip steady and pull the front grip gently toward the back finger grip. This action causes the retractable sheath to draw back in a controlled, gradual manner. As the retractable sheath slides back, the prosthesis is exposed. The prosthesis expands in diameter and shortens in length as it emerges.

   When the front finger grip reaches the back security button, the prosthesis is exposed, but not released from the holding mechanism. This offers the opportunity to move the telescope and to make a final check of the position of the prosthesis. It is important to keep the partially deployed prosthesis aligned with the delivery instrument. Moving the delivery instrument at an angle that puts traction on the exposed prosthesis may cause the prosthesis to release prematurely.

   Visualize the entire length of the urethral stricture to ensure that the prosthesis is situated in the intended position. The prosthesis should cover the entire length of the urethral stricture. The implanted prosthesis should not cover the external sphincter.

   ***Caution: Ensure that the prosthesis does not extend into the external sphincter. Placing the prosthesis in the external sphincter may cause the patient to be incontinent.***

   If the prosthesis is not in the intended position, resheathe the prosthesis by advancing the delivery instrument's retractable sheath until it completely covers the prosthesis. To do this, withdraw the delivery instrument slightly while gently pushing the front finger grip away from the back finger grip until the first security button re-engages with an audible click. As this is done, the retractable sliding sheath encompasses the prosthesis. With the prosthesis securely inside the delivery instrument shaft, the physician may move the instrument to the intended position in the urethra.

   ***Caution: Failure to resheathe the prosthesis before advancing the delivery instrument will result in compression of the prosthesis and possible trauma to the urethra.***

4. *Release*

   Before releasing the prosthesis, position the telescope to view the prosthesis at the proximal end of the stricture. Confirm with direct vision that the prosthesis overlaps the stricture by at least 5mm and that the prosthesis does not impinge on the external sphincter.

   Release the prosthesis from the holding mechanism by pressing the rear security button and completely withdrawing the retractable sliding sheath. Use the middle finger to move the front finger grip. The index finger presses the rear security button.

   ***Caution: Do not attempt to remount the prosthesis onto the deployment instrument. Attempting to insert a remounted prosthesis into the urethra can cause improper function of the deployment instrument and result in trauma to the urethra.***

5. *Withdrawal of the Delivery Instrument*

   Before beginning to withdraw the delivery instrument, move the telescope back to ensure the delivery instrument is aligned with the distal end of the prosthesis and verify that the prosthesis is fully released.

   Pull gently on both finger grips to distance the delivery instrument shaft from the released prosthesis. Observe that the prosthesis does not move out of position as the delivery instrument pulls away from it. Using the back finger grip as a stabilizer, pull the delivery instrument away from the correctly placed prosthesis just enough to ensure that the prosthesis is completely free of the holding mechanism. Some physicians rotate the delivery instrument slightly while viewing the prosthesis through the telescope. In this way, they ensure that the prosthesis is completely free of the delivery instrument.

   Retract the telescope into the delivery instrument, taking care not to let it touch the prosthesis.

   Withdraw the delivery instrument from the urethra, using care not to displace the prosthesis.

Proceeding with care, perform normal endoscopy using a 17Fr or smaller cystoscope. Manipulate the cystoscope carefully and avoid contact with the prosthesis. Observe carefully to ensure that the prosthesis does not move out of position. Ensure that the prosthesis completely covers the stricture. The prosthesis should overlap the stricture by 5mm or more at each end.

***Caution: Passing a cystoscope through the prosthesis may displace the prosthesis.***

## Placing Multiple Stents

If more than one stent is required to adequately cover the strictured area, the first stent placed should cover the most proximal (nearest the external sphincter) end of the stricture. Additional stents may then be placed following steps 1-5 above. The additional stent(s) should overlap the previously placed stent by at least 5mm.

***Caution: Exercise care with instrumentation to ensure that the first prosthesis is not dislodged while placing a second prosthesis.***

## Adjusting the Position of a Released Prosthesis

***Caution: Any repositioning of a released prosthesis must be performed with care in order not to cause trauma to the urethra.***

1. *Repositioning a Prosthesis Placed Too Far Proximally*

   If the released prosthesis appears to extend too far into the external sphincter or too far proximal from the urethral stricture, it is possible to reposition the prosthesis using the following procedure:

   Grasp several rows of wire with a biopsy forceps, not less than 2mm from the distal end of the prosthesis. Gently pull the prosthesis into the intended position. Grasping and pulling only a single wire may cause the wire mesh prosthesis to unravel or break. Confirm position endoscopically by visualizing some distance between the external sphincter and prosthesis.

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2. *Repositioning a Prosthesis Placed Too Far Distally*

   If the released prosthesis appears to be positioned in the bulbar scrotal junction or if it does not extend far enough within the urethral stricture, it is possible to reposition the prosthesis using the following procedure:

   With urologic forceps, grasp several rows of wire near the end of the prosthesis closest to the proximal end of the urethral stricture. Push the prosthesis until it extends at least 5mm proximal to the urethral stricture.

## Postoperative Procedures

Prescribe prophylactic antibiotics to the dose and duration typically prescribed for urethrotomy or dilation. If the patient is unable to void, place a suprapubic tube for drainage.

***Caution:*** *Use care to avoid contact that would displace the prosthesis or modify its position. Do not use a urethral catheter until the prosthesis is stabilized by epithelial ingrowth. Inserting a catheter into the urethra before epithelium has grown over the prosthesis may cause the prosthesis to move out of position and may cause trauma to the urethra. In emergency situations, suprapubic urinary catheterization may be used, however, no transurethral instruments should be used until a physician familiar with the UroLume prosthesis can check its stability. If possible, patients should be seen by a physician familiar with the UroLume prosthesis when the implanting physician is not available, until epithelialization has occurred.*

## Removing a Released Prosthesis

With a urologic alligator forceps, grasp three to four diamonds of wire at the distal end of the prosthesis. If more than one prosthesis is to be removed, begin with the most recently placed prosthesis. Gently pull the prosthesis. As the prosthesis is drawn out, it elongates and narrows allowing the physician to withdraw it from the urethra.

*Note: Grasping and pulling only a single wire may cause the wire mesh prosthesis to unravel or break. In this instance, each wire must be removed individually. Each prosthesis consists of 24 wire filaments. Confirm with endoscopy and fluoroscopy that all wire filaments are retrieved.*

## Prosthesis Removal After Epithelialization

***Caution: A prosthesis that has epithelialized must be resected before it can be removed.***

To resect urethral tissue from a prosthesis that has epithelialized, use a low current setting and employ the resectoscope loop with a continuous movement. Prolonged contact between the loop and the prosthesis may cause wires to melt. After the resected tissue is removed, the procedure described above is used to remove the prosthesis from the urethra.

***Caution: Use care in handling the explanted prosthesis to prevent the prosthesis from puncturing the protective surgical gloves.***

***Should a UroLume prosthesis ever be extracted after placement, the prosthesis must be returned to AMS. Contact your AMS representative for returned goods and warranty information.***

If the prosthesis is inadvertently deployed, do not attempt to reassemble it into the delivery instrument. In this instance, contact your AMS representative to return the prosthesis and delivery instrument.

***Caution: Do not attempt to remount the prosthesis into the delivery instrument. Attempting to remount the prosthesis into the delivery instrument can cause the delivery instrument to function incorrectly and cause trauma to the urethra.***

## Imaging of the Prosthesis

The UroLume prosthesis may be imaged using ultrasound, magnetic resonance imaging (MRI) and plain film radiogram.

[redacted]

## Returning Inventory and Warranty Information

Before returning any stents, whether explanted or unused and sterile, customers must fill out the Return Goods Form located on the last page of the Patient Information Form. Follow all of the instructions on the form carefully and be sure that the stents have been thoroughly cleaned before returning them to American Medical Systems, Inc.

In all cases, obtaining credit or percentage of credit for a returned stent is subject to approval under the terms of the AMS Return Goods Policy and the AMS Limited Warranty Policy. For complete information regarding these policies, contact the AMS Customer Service Department.

This document is written for professional medical audiences.

American Medical Systems, Inc. periodically updates product literature. If you have any questions regarding the currency of this information, please contact American Medical Systems.

*Reference*

1. Haylen, B.T., Ashby, D., Sutherst, J.R., Frazer, M.I., West, C.R.: MAXIMUM AND AVERAGE URINE FLOW RATES IN NORMAL MALE AND FEMALE POPULATIONS - THE LIVERPOOL NOMOGRAMS; British Journal of Urology; July 1989, Vol. 64, No. 1, pp. 30-38.

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Pfizer

American Medical Systems

Manufactured by SCHNEIDER AG for American Medical Systems, Inc.

Patented, and U.S. and international patents pending.



Publication Date: 03/02/96
Order Number: 2330048

# Important Information For Patients Considering An AMS UroLume™ Endoprosthesis

You are currently evaluating the treatment alternatives for your recurrent bulbar urethral stricture disease. After discussing all your options (including dilation, urethrotomy, urethroplasty, or a urethral stent) with your physician, you are now considering having a UroLume™ Endoprosthesis inserted in your urethra.

This brochure will answer many of your questions about the UroLume prosthesis, as well as the insertion procedure. It is intended to supplement the discussions you have with your urologist. Additionally, you will learn more about the risks and benefits of the UroLume prosthesis. A glossary of medical terms is provided at the end of this brochure.

All of this information will help you make an informed decision about your treatment to relieve the symptoms of your recurrent bulbar urethral stricture disease. If you have any additional questions about your stricture disease or the information provided in this brochure, be sure to ask your physician.

Pfizer
American Medical Systems

# About the AMS UroLume™ Endoprosthesis

The AMS UroLume™ Endoprosthesis is a braided, wire mesh tube that is placed in the urethra to hold it open (Figure 1). It is used to treat men with urinary obstruction due to recurrent benign urethral stricture disease. The device stays in the body permanently.

The UroLume prosthesis is an alternative treatment for patients in whom other treatment methods, including dilation, urethrotomy, and/or urethroplasty, have been unsuccessful - the treatment did not initially relieve the stricture disease or the stricture has returned, needing another treatment.

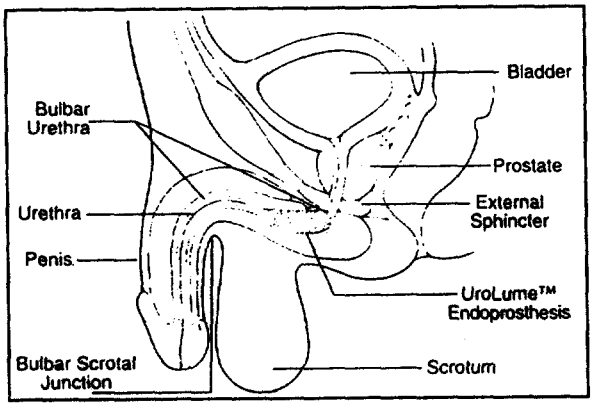


**Figure 1: Urethral Stricture Treated with the UroLume Endoprosthesis**

As your physician has already explained, you have a urinary obstruction, called a stricture. The stricture causes your urethra to become narrower and makes it more difficult for your urine to get through. The UroLume prosthesis is designed to treat men, like you, who have recurrent bulbar urethral strictures (strictures between the external sphincter and the bulbar scrotal junction) that are shorter than 3.0cm.

# How the Prosthesis Works

The UroLume prosthesis has two parts: the prosthesis itself and the tool your physician uses to place it in your urethra. As mentioned previously, the prosthesis is a braided mesh tube that is made of a high strength metal wire (Figure 2). The braided mesh design allows the tube to expand in width once it is inserted in the bulbar urethra so that it will hold the area of the stricture open. This allows urine to easily flow from the bladder to the outside of the body.

Because the UroLume prosthesis expands in width, it presses against the wall of the urethra and prevents the prosthesis from moving within the urethra. This also allows your urethral tissue to grow, and eventually, cover the wire mesh. Urethral tissue growth over the prosthesis is expected over time. If, however, the tissue does not completely cover the wire mesh, stones may develop on the prosthesis. If stones do develop, an endourethral procedure may be necessary to remove them.

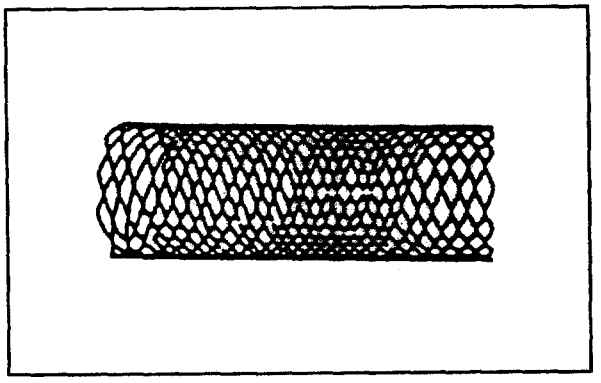

**Figure 2: The UroLume Endoprosthesis**

The second part of the UroLume prosthesis, the insertion tool (Figure 3), is used to place the prosthesis inside your urethra. This tool compresses the wire mesh prosthesis to make it smaller than your urethra so that it is easier to insert. The tool's hollow inner tube allows your physician to use a telescope to see inside your urethra and to see the exact location of your stricture. Mounted on the tool's inner tube, the prosthesis is exposed and released when your physician pulls the finger grips together. Once the UroLume prosthesis is released in your urethra, it is designed to expand in width to hold the stricture open.

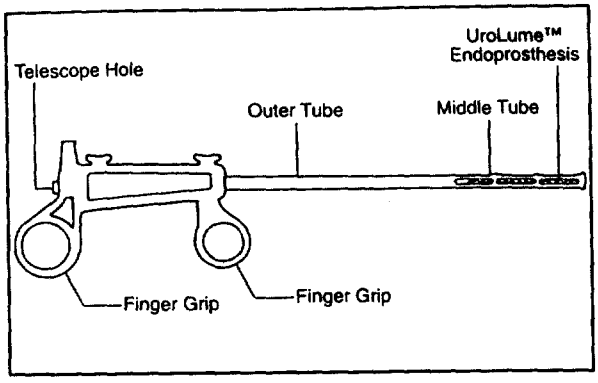


**Figure 3: The UroLume Endoprosthesis Insertion Tool**

# About the Procedure

Before the procedure, your physician may decide to give you a local anesthesia so that you remain awake during insertion of the UroLume prosthesis. Or, you may receive a general anesthesia so that you are asleep for the procedure. The telescope that your physician will use is the same kind used during a routine urethroscopy procedure that you have already had in the past. To you, the insertion procedure may seem very similar to a urethroscopy.

Your physician starts the procedure by inserting a small urethroscope through the end of your penis. The urethroscope helps the physician see and measure the stricture to determine what size UroLume prosthesis you will need. The physician will also dilate the strictured area and/or perform a urethrotomy to make it easier to insert the prosthesis.

Next, your physician places the UroLume prosthesis' insertion tool into your urethra through the end of your penis. Using a telescope inserted through the tool's hollow inner tube, the physician looks inside your urethra and moves the tool to where your stricture is located.

When everything is positioned correctly, the physician releases the UroLume prosthesis from the insertion tool. Once released, the device expands and presses against the walls of your urethra. The insertion tool is removed, but the UroLume prosthesis stays inside you to hold your urethra open. If one prosthesis does not completely cover your stricture, your physician may insert additional UroLume prostheses to provide complete coverage.

# What to Expect After Insertion

Your physician will give you a medical information card after the insertion procedure. This card contains important information about the UroLume prosthesis that was just inserted. Remember to always carry this card with you.

After the insertion procedure, your physician will want you to take antibiotic drugs to reduce your risk of infection. It is very important for you to take all the medicine as prescribed. Your physician will probably also advise you to wait at least four weeks before resuming sexual intercourse or other sexual activities. The exact period of time will depend on your medical condition and history. This is important because it minimizes the possibility of pain, infection or bleeding and prevents the UroLume prosthesis from moving out of position. Be sure to follow all of your physician's instructions carefully.

In the weeks following the insertion procedure, you may dribble urine after going to the bathroom. If this dribbling becomes a concern for you, your physician may be able to provide advice about how to remove urine from your urethra more completely.

Some men also experience blood in their urine or pain during the first few weeks after insertion of the UroLume prosthesis. If you have bleeding or pain that seems to get worse over time, be sure to contact your physician.

Men who frequently ride bicycles or horses or who participate in other activities that put similar stresses on the urethra, may experience some mild discomfort during these activities after insertion of the UroLume prosthesis. Many cyclists have been able to ease

their discomfort by using a large bicycle saddle.

Because physical manipulation of the UroLume prosthesis may cause pain or movement of the prosthesis, you should avoid applying unnecessary pressure to the area where the prosthesis is located.

Catheters or other instruments should not be placed into the urethra until the UroLume prosthesis has been stabilized by the growth of urethral tissue. If instrumentation is needed to empty your bladder, your physician may decide to use a suprapubic catheter. You should inform treating physicians that you have a UroLume prosthesis implanted in your urethra and show them your medical information card.

Contact your physician if you experience fever, increased pain, or difficulty going to the bathroom. Also talk to your physician about any other questions or concerns you have after the UroLume prosthesis insertion procedure.

# Removing the UroLume Endoprosthesis

If necessary, the UroLume prosthesis can be removed. For example, if your physician determines during the insertion procedure that the prosthesis is not in the correct position, it can be removed using forceps. To do this, your physician will use forceps to grasp the prosthesis' wire mesh and pull the forceps and the UroLume prosthesis out of your urethra. As the prosthesis is pulled, it becomes longer and narrower, making removal from your urethra possible. If, however, the physician does not grasp enough of the prosthesis with the forceps, the wire mesh can come apart or break. If this should occur, your physician will need to remove each wire individually and ensure that all of the wires are removed.

If the UroLume prosthesis needs to be removed after your urethral tissue has covered the prosthesis, your physician will need to remove this tissue before removing the prosthesis. After loosening the prosthesis from the tissue, the UroLume prosthesis can be removed using forceps as described above.

Urethral trauma may occur during the removal process. During the clinical studies, however, the trauma experienced during prosthesis removal was mild. Additionally, there has been no known increase in the formation of strictures for patients who had the UroLume prosthesis removed. Typically, the stricture returns in the area of the urethra that was covered by the prosthesis - the condition that was present before the UroLume prosthesis was ever inserted.

# Advantages of the UroLume Endoprosthesis

*Improved Flow of Urine*

Clinical studies show that the UroLume prosthesis is effective and significantly improves the flow of urine out of the body.

*Reduced Symptoms of Stricture Disease*

Most patients notice a significant improvement in the symptoms associated with their stricture disease, including hesitancy, poor flow, incomplete emptying, frequency, getting up to go to the bathroom at night, painful urination, two stage voiding (starting urine flow and then stopping and starting again) and increased voiding time.

*Reduced Need for Further Treatment*

After insertion of the UroLume prosthesis, most patients do not require further treatment for their stricture for at least two years. Clinical studies, in fact, indicated a dramatic reduction in the need for further treatment of the strictures in the two years following prosthesis insertion as compared to the need for stricture treatments in the two years prior to insertion.

*Easy Insertion*

Most UroLume prosthesis insertions have been performed as outpatient procedures, reducing the time spent in a hospital setting. For additional information about the benefits of the UroLume prosthesis, please contact your physician.

## Risks Associated with the UroLume Endoprosthesis

*Urinary Incontinence*

Misplacement of the prosthesis within your external sphincter can cause urinary incontinence.

*Infection*

Your UroLume prosthesis may need to be removed if an infection develops at the prosthesis site.

*Trauma Caused by Prosthesis Removal*

Removal of your prosthesis after it is covered in urethral tissue could cause trauma to your urethra.

*Trauma Caused by Urethral Instruments*

Urethral instruments, such as a urethroscope or a catheter, could cause trauma to your urethra or dislodge your UroLume prosthesis.

*Bleeding*

You may experience blood in your urine for the first few weeks after the procedure.

*Encrustation*

If your urethral tissue does not grow to cover the UroLume prosthesis over time, your prosthesis may become encrusted. If so, the prosthesis may need to be removed.

*Migration/Shortening*

The UroLume prosthesis may migrate (move) and/or shorten within your urethra. If this occurs, the prosthesis may not completely bridge the strictured area of your urethra.

*Obstruction*

Tissue that grows through the UroLume prosthesis may cause an obstruction in your urethra. This may limit the flow of urine from your body. Urethral tissue growth that causes an obstruction may require removal of that tissue and, possibly, the prosthesis itself.

*Discomfort and Other Symptoms Following the Procedure*

You can expect mild discomfort, some dribbling, urgency, and/or the need to urinate often during the night for the first few weeks after insertion of the UroLume prosthesis. In most cases, these symptoms will end or diminish on their own.

*Painful Erections and/or Ejaculation*

You may experience some pain with erections and/or ejaculation after insertion of the UroLume prosthesis. In most cases, these symptoms will end or diminish on their own.

*Changes in Benign Growth*

Changes of benign growth within the urethra may occur after insertion of the UroLume prosthesis that may require a biopsy - especially for patients who have had a previous skin graft urethroplasty.

*Suprapubic Catheter*

There may be times when a suprapubic catheter would be needed.

You should also be aware that, during the clinical study of the UroLume prosthesis, a patient who had an abnormal looking stricture before receiving the prosthesis was found to have urethral cancer several months after the insertion. Although it appears that this patient had the cancer before insertion of the UroLume prosthesis, there may be some risk of developing urethral cancer.

Be sure to discuss any additional possible risk with your physician.

# Glossary of Terms

**ANESTHESIA:** The loss of all sensation in a specific area of the body (local anesthesia) or throughout the entire body (general anesthesia).
**ANTIBIOTIC:** A medication used to prevent or treat infection.
**BENIGN:** Not caused by cancer.
**BULBAR SCROTAL JUNCTION:** The area of the urethra where the penis meets the body.
**BULBAR URETHRA:** The area of the urethra between the external sphincter and the bulbar scrotal junction.
**CATHETER:** A tube inserted through the urethra and into the bladder to allow urine to flow out of the body.
**DILATION:** Enlarging the diameter of a strictured area by passing tubes of gradually increasing width through the strictured area.
**DRIBBLING AFTER URINATION:** The passage of a limited amount of urine after the completion of urination.
**EJACULATION:** The discharge of semen from the urethra.
**ENCRUSTED:** Stone-like formations that attach to the prosthesis.
**ENDOURETHRAL:** Within the urethra.
**EXTERNAL SPHINCTER:** A muscle around the urethra that opens and closes to allow the flow of urine.
**FORCEPS:** An instrument resembling tweezers that is used to grasp objects within the urethra.
**FREQUENCY:** A need to urinate often.
**HESITANCY:** Delayed start of urine flow after the need to urinate is felt and the person wishes to urinate.
**INCONTINENCE:** The inability to control the flow of urine from the body, resulting in the involuntary passage of urine.
**INSTRUMENTATION:** Using medical tools within the urethra.
**MANIPULATION:** Applying unnecessary pressure to the area where the prosthesis is located.
**OBSTRUCTION:** A blockage of the urethra that restricts the flow of urine out of the body.
**PROSTHESIS:** An artificial replacement (the implanted device) for a body part.
**RECURRENT BULBAR URETHRAL STRICTURE:** A narrowing of the bulbar urethra that keeps returning even after treatment.
**STRICTURE:** A narrowing of the urethra that limits the flow of urine.
**STABILIZED:** When the prosthesis is held in position by urethral tissue.
**SUPRAPUBIC CATHETER:** A catheter placed through your stomach to allow the flow of urine from the bladder.
**TELESCOPE:** An instrument used to view the inside of the urethra.
**TWO STAGE VOIDING:** Interrupted urine flow, resulting in urine flow that starts, stops, and starts again.
**URETHRA:** The tube that moves urine from the bladder, through the penis, and outside the body.
**URETHROPLASTY:** A procedure to cut out the strictured area of the urethra and either replace it with a graft or connect the two ends of the urethra where the stricture was removed.
**URETHROSCOPE:** A special telescope used to view the inside of the urethra.
**URETHROSCOPY:** A procedure to look inside the urethra using a urethroscope.
**URETHROTOMY:** A procedure to enlarge the diameter of the urethra by making a series of small cuts through the strictured area.
**URGENCY:** A strong desire to urinate immediately.
**VOIDING:** Urination.


American Medical Systems, Inc.
Pfizer Hospital Products Group
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FAX: (1) 612-930-6592


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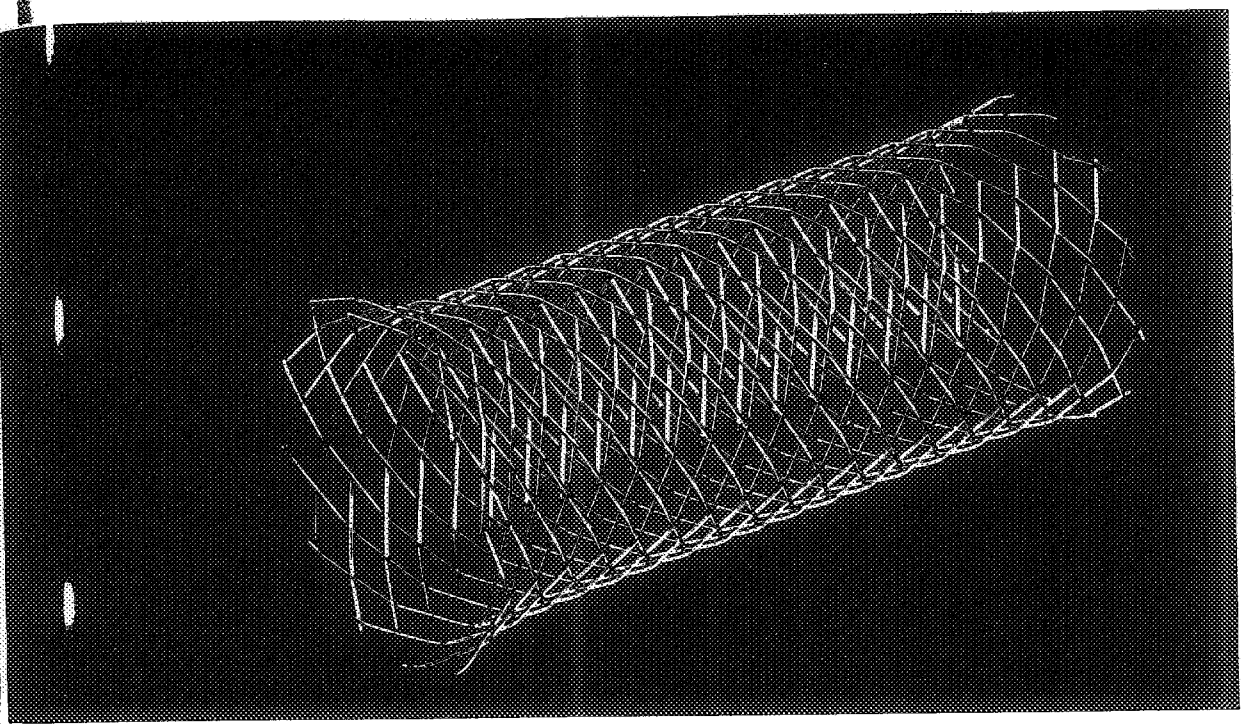
Publication Date: April 1996
Order Number: 23600014

# UroLume™
*Endoprosthesis*

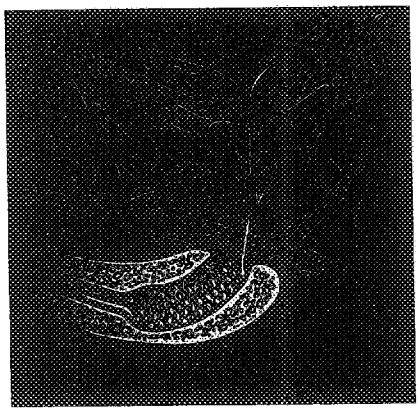


# *Simply brilliant.*

## *A New Approach to Recurrent Bulbar Urethral Strictures*

By relieving the obstruction associated with recurrent bulbar urethral strictures, the UroLume prosthesis increases peak flow, decreases patients' symptoms while offering a cost effective method of treating recurrent urethral strictures.

- Easy to place.
- Self-expanding, flexible design.
- Designed for patient comfort.
- Demonstrated performance in clinical studies.



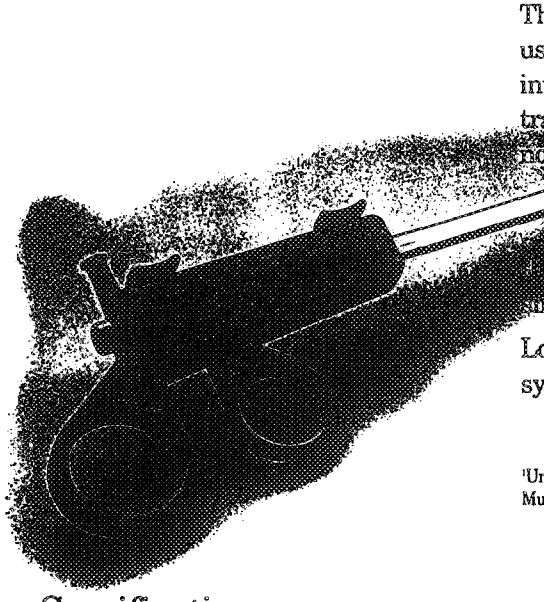
The UroLume prosthesis is positioned transurethrally, using a specially designed delivery system that allows complete endoscopic viewing. The delivery system is designed for increased accuracy in placement.

Made of corrosion resistant superalloy wire, the woven mesh cylinder expands inside the urethra. Epithelial tissue grows over the mesh surface, holding the flexible cylinder in place. The UroLume prosthesis is radiopaque and non-magnetic. It can be imaged using magnetic resonance imaging (MRI), ultrasound, and plain film x-rays.

Pfizer

American Medical Systems

## *UroLume prosthesis delivery instrument*



The placement procedure can be done under local or general anesthesia. There is usually no hospital stay [illegible]. Placement of the UroLume prosthesis is a less invasive procedure than [illegible] urethroplasty and consequently can be less traumatic to the [illegible] patient. Patients can usually resume mo[illegible] normal [illegible] activities within a few days.

[illegible]roLume prosthesis creates an open lumen by pressing against [illegible]ral wall with radial force. As the epithelium grows over the prosthesis, [illegible] becomes incorporated within the urethral wall, providing a flexible, smooth and open lumen for the urethra, minimizing recurring obstruction.

Long term experience shows sustained improvement in urine flow, improved symptom score and reduced retreatment rate in almost all of the patients studied[1]

[1]UroLume Endourethral Prosthesis For The Treatment Of Urethral Stricture Disease: Long-Term Results Of The North Am[illegible] Multicenter UroLume Trial. Badlani GH, Press SM, Defalco A, Oesterling JE and Smith AD; Urology 45 (No. 5): 846-856, May 199[illegible]

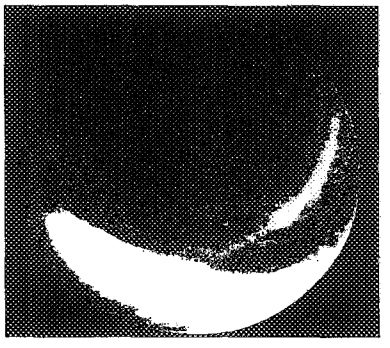
## *Specifications*

The braided mesh cylinder is made of biocompatible superalloy wire. It is available in 2cm, 2.5cm and 3cm lengths. The prosthesis expands to a maximum diameter of 14mm regardless of length.

For a list of warnings, precautions, and contraindications regarding this prosthesis, refer to the ***Instructions For Use*** provided in the product package, contact your local AMS Representative, or contact American Medical Systems, Inc. at 1-800-328-3881, ext. 6469.

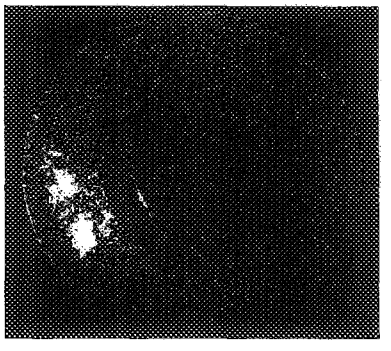
This document is written for professional medical audiences. Contact American Medical Systems, Inc. for lay publications. American Medical Systems periodically updates product literature. If you have questions regarding the currency of this information, please contact American Medical Systems.

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.



*Six months post implant*

The lumenal surface of t[illegible] urethra is covered with epithelial tissue although the mesh pattern can still be seen.



*One year post implant*

The UroLume prosthesis is well covered with epithelial tissue, providing a smooth lining of the urethra.



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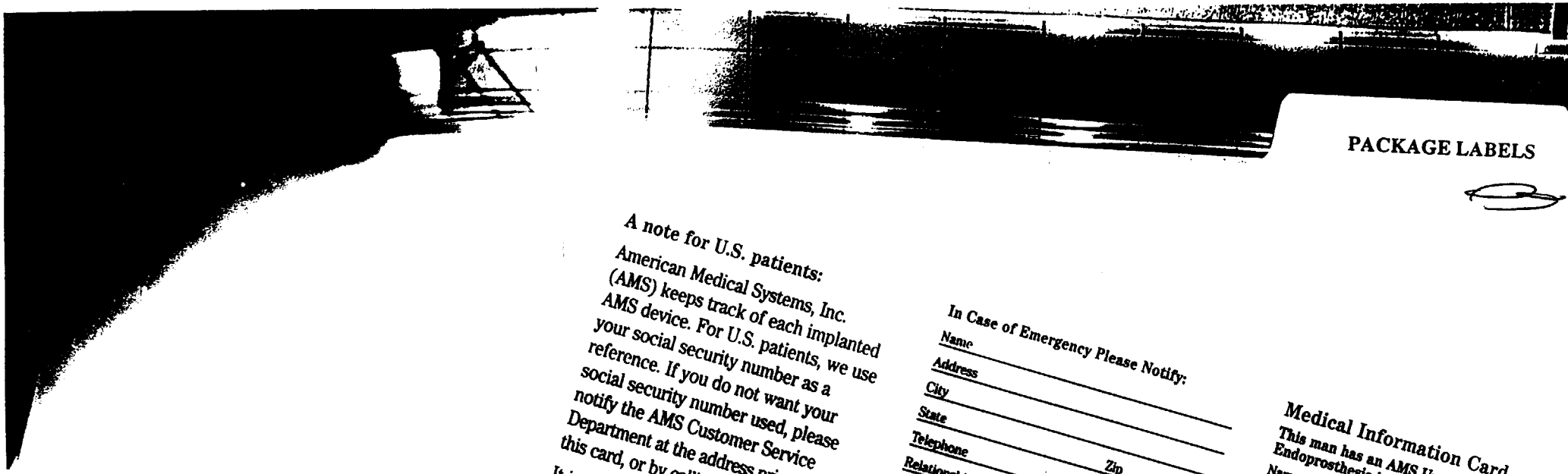

*A note for U.S. patients:*

American Medical Systems, Inc. (AMS) keeps track of each implanted AMS device. For U.S. patients, we use your social security number as a reference. If you do not want your social security number used, please notify the AMS Customer Service Department at the address printed on this card, or by calling (800) 328-3881.

It is important that your record is accurate and current. Please help us keep your file up-to-date by notifying AMS any time you change your address or if you change your name.

Thank you for your considerate attention to this important part of having an implanted AMS UroLume Endoprothesis.

**In Case of Emergency Please Notify:**

Name
Address
City
State
Telephone Zip
Relationship

or

Name
Address
City
State,
Telephone Zip
Relationship

If the patient or relative is unable to provide emergency information regarding the prosthesis, please contact:

Dr.
Telephone
Hospital

(Use ballpoint pen, let it dry)

## Medical Information Card

**This man has an AMS UroLume™ Endoprosthesis inserted in his bulbar urethra.**

Name
Soc.Sec. No.
Address
City
State
Telephone Zip
Hospital
Telephone
Implanting Physician
Implant Date
Number of Stents Implanted
Hospital File No.
Health Insurance
Policy Number

(Use ballpoint pen, let it dry)

Pfizer

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DZ820049

American Medical Systems

Pfizer Hospital Products Group
10700 Bren Road West
Minnetonka, MN 55343 U.S.A.

**DO NOT CATHETERIZE OR PLACE AN ENDOSCOPIC OR TRANSURETHRAL TOOL IN THE PATIENT UNTIL A PHYSICIAN HAS EVALUATED THE STABILITY OF THE PROSTHESIS.**

The UroLume prosthesis is a braided superalloy mesh cylinder which expands in the urethra to hold open strictures that obstruct urine flow. In the course of healing after implantation, the prosthesis becomes completely covered with epithelial tissue. If possible, this patient should be seen by a physician when the UroLume prosthesis is not available, with the UroLume prosthesis. If the physician has occurred. implanting physician has occurred. until epithelialization has occurred.

**Imaging**

The UroLume prosthesis can be imaged using ultrasound, plain film radiograms, and magnetic resonance imaging.

**Precautions**

1. Do not catheterize or perform any endoscopic or transurethral procedures until the prosthesis has stabilized. In emergency situations, the suprapubic urinary catheterization may be used, however, no transurethral instruments should be used until a physician familiar with the UroLume prosthesis can check its stability. The UroLume prosthesis or catheter may be used only if epithelial tissue has stabilized the prosthesis. Manipulate the instrument gently through the prosthesis to avoid any contact that would modify its position, or trauma to the urethra may result.

2. A cystoscope or catheter may be used only if epithelial tissue has stabilized the prosthesis. Manipulate the instrument gently through the prosthesis to avoid any contact that would modify its position, or trauma to the urethra may result.

3. Do not attempt removal or manipulation of the implanted prosthesis. If the prosthesis must be removed, contact the implanting physician.

urethral bulbar

OUTER BOX

End
bull

# Endoprosthesis for recurrent bulbar urethral stricture

2.0 cm

Produc

Product No. **AMS-72402010** Lot No. **5Y0637**

End
Pro
End
Pro
Pró

Endourethral prosthesis for bulbar urethral stricture
Prothèse endo-urétrale pour la sténose urétrale bulbaire
Endourethrale Prothese für bulbäre Harnröhrenstriktur
Protesi endouretrale per stenosi dell'uretra bulbare
Prótesis endouretral para estenosis uretral bulbar

Refere
Diamètr
Referer
Diamètr
Diamètr

Reference diameter
Diamètre référence
Referenzdurchmesser
Diametro di riferimento
Diámetro de referencia

**14.0 mm**

Reference length
Longueur référence
Referenzlänge
Lunghezza di riferimento
Longitud de referencia

**2.0 cm**

Produ
No. d
Produ
No. d
No. d

Product No.
No. de produit
Produkt Nr.
No. di prodotto
No. del producto

**AMS-72402010**

Lot No.
No. de lot
Lot Nr.
No. di lotto
No. de lote

**5Y0637**

Disp
Syst
Einf

Disposable delivery system
Système d'insertion à usage unique
Einführsystem zum Einmalgebrauch

Sistema di collocamento monouso
Dispositivo de colocación desechable

Usable
Longue
Brauchb
Lunghe
Largo u

Usable shaft length
Longueur utilisable de l'instrument
Brauchbare Instrumentenlänge
Lunghezza utilizzabile di strumento
Largo utilizable del instrumento

**20.8 cm**

Telescope compatibility
Télescope compatible
Kompatibles Teleskop
Compatibilità del telescopio
Compatibilidad del telescopio

**28/30 cm**

Manuf./
Date de
Prod./S
Data di
Fecha d

Manuf./Sterilization date
Date de prod./stérilisation
Prod./Sterilisationsdatum
Data di prod./sterilizzazione
Fecha de prod./esterilización

**05/1996**

Use before expiration date
Date d'échéance
Verwendbar bis
Data di scadenza
Usese antes de

**05/1996**

Dose of radiation
Dose de radiations
Bestrahlungsdosis
Dose di radiazioni
Dosis de radiaciones

**2.5 Mrad**

Steril
Labora
Steril
Labora
Labora

Sterilization facility
Laboratoire de stérilisation
Sterilisationsstätte
Laboratorio di sterilizzazione
Laboratorio de esterilización

STUDER AG
CH-4658 DAENIKEN

>6>8+E110AMS7240201006

>6>82280105965Y0637X06

88001

880018-001 A

OUTER BOX

# Endoprosthesis for recurrent bulbar urethral stricture

2.5 cm

cm

Product No. **AMS-72402011** Lot No. **5Y0638**

Endourethral prosthesis for bulbar urethral stricture
Prothèse endo-urétrale pour la sténose urétrale bulbaire
Endourethrale Prothese für bulbäre Harnröhrenstriktur
Protesi endouretrale per stenosi dell'uretra bulbare
Prótesis endouretral para estenosis uretral bulbar

| | | | |
|---|---|---|---|
| Reference diameter<br>Diamètre référence<br>Referenzdurchmesser<br>Diametro di riferimento<br>Diámetro de referencia | **14.0 mm** | Reference length<br>Longueur référence<br>Referenzlänge<br>Lunghezza di riferimento<br>Longitud de referencia | **2.5 cm** |
| Product No.<br>No. de produit<br>Produkt Nr.<br>No. di prodotto<br>No. del producto | **AMS-72402011** | Lot No.<br>No. de lot<br>Lot Nr.<br>No. di lotto<br>No. de lote | **5Y0638** |

Disposable delivery system — Sistema di collocamento monouso
Système d'insertion à usage unique — Dispositivo de colocación desechable
Einführsystem zum Einmalgebrauch

| | | | |
|---|---|---|---|
| Usable shaft length<br>Longueur utilisable de l instrument<br>Brauchbare Instrumentenlänge<br>Lunghezza utilizzabile di strumento<br>Largo utilizable del instrumento | **19.5 cm** | Telescope compatibility<br>Télescope compatible<br>Kompatibles Teleskop<br>Compatibilità del telescopio<br>Compatibilidad del telescopio | **28/30 cm** |

| | | | | | |
|---|---|---|---|---|---|
| Manuf./Sterilization date<br>Date de prod./stérilisation<br>Prod./Sterilisationsdatum<br>Data di prod./sterilizzazione<br>Fecha de prod./esterilización | **05/1996** | Use before expiration date<br>Date d'échéance<br>Verwendbar bis<br>Data di scadenza<br>Usese antes de | **05/1996** | Dose of radiation<br>Dose de radiations<br>Bestrahlungsdosis<br>Dose di radiazioni<br>Dosis de radiaciones | **2.5 Mrad** |

Sterilization facility
Laboratoire de stérilisation
Sterilisationsstätte
Laboratorio di sterilizzazione
Laboratorio de esterilización

STUDER AG
CH-4658 DAENIKEN

>6>8+E110AMS7240201107

>6>822801059 65Y0638X07

880018-001 A

OUTER BOX

# Endoprosthesis for recurrent bulbar urethral stricture

3.0 cm

Product No. **AMS-72402012** Lot No. **5Y0639**

Endourethral prosthesis for bulbar urethral stricture
Prothèse endo-urétrale pour la sténose urétrale bulbaire
Endourethrale Prothese für bulbäre Harnröhrenstriktur
Protesi endouretrale per stenosi dell'uretra bulbare
Prótesis endouretral para estenosis uretral bulbar

| | | | |
|---|---|---|---|
| Reference diameter<br>Diamètre référence<br>Referenzdurchmesser<br>Diametro di riferimento<br>Diámetro de referencia | **14.0 mm** | Reference length<br>Longueur référence<br>Referenzlänge<br>Lunghezza di riferimento<br>Longitud de referencia | **3.0 cm** |
| Product No.<br>No. de produit<br>Produkt Nr.<br>No. di prodotto<br>No. del producto | **AMS-72402012** | Lot No.<br>No. de lot<br>Lot Nr.<br>No. di lotto<br>No. de lote | **5Y0639** |

Disposable delivery system — Sistema di collocamento monouso
Système d'insertion à usage unique — Dispositivo de colocación desechable
Einführsystem zum Einmalgebrauch

| | | | |
|---|---|---|---|
| Usable shaft length<br>Longueur utilisable de l instrument<br>Brauchbare Instrumentenlänge<br>Lunghezza utilizzabile di strumento<br>Largo utilizable del instrumento | **19.5 cm** | Telescope compatibility<br>Télescope compatible<br>Kompatibles Teleskop<br>Compatibilità del telescopio<br>Compatibilidad del telescopio | **28/30 cm** |

| | | | | | |
|---|---|---|---|---|---|
| Manuf./Sterilization date<br>Date de prod./stérilisation<br>Prod./Sterilisationsdatum<br>Data di prod./sterilizzazione<br>Fecha de prod./esterilización | **05/1996** | Use before expiration date<br>Date d'échéance<br>Verwendbar bis<br>Data di scadenza<br>Usese antes de | **05/1996** | Dose of radiation<br>Dose de radiations<br>Bestrahlungsdosis<br>Dose di radiazioni<br>Dosis de radiaciones | **2.5 Mrad** |

Sterilization facility
Laboratoire de stérilisation
Sterilisationsstätte
Laboratorio di sterilizzazione
Laboratorio de esterilización

STUDER AG
CH-4658 DAENIKEN

>6>8+E110AMS7240201208

>6>82280105965Y0639X08

680018-001 A

# UroLume™

## Endourethral Prosthesis

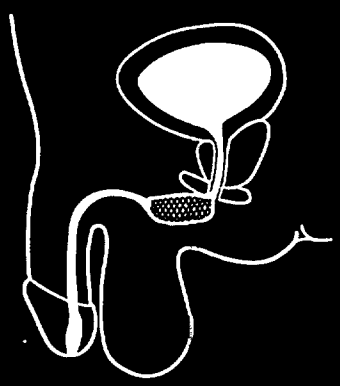
**Endourethral Prosthesis For Bulbar Urethral Stricture**

**Prothèse endo-urétrale pour la sténose urétrale bulbaire**

**Endourethrale Prothese für bulbäre Harnröhrenstriktur**

**Protesi endouretrale per stenosi dell'uretra bulbare**

**Prótesis endouretral para estenosis uretral bulbar**



# Endourethral Prosthesis
# Prothèse endo-urétrale
# Endourethrale Prothese
# Protesi endouretrale
# Prótesis endouretral

**CONTENTS STERILE.**
Contents: one (1) Urolume™ Endourethral Prosthesis with Delivery System
**DO NOT RESTERILIZE.**
**FOR ONE TIME USE ONLY.**
Contents of the sealed tray have been sterilized and will remain sterile, unless exposed to a nonsterile environment. Gamma radiation sterilized.
**WARNING: Carefully read the instructions included prior to use. These products are returnable only with prior approval from American Medical Systems, Inc. Before returning product, contact your local American Medical Systems representative.**

**CONTENU STERILE.**
Contenu: une (1) prothèse Urolume™ endo-urétrale avec système d'insertion
**NE PAS RESTERILISER.**
**USAGE UNIQUE EXCLUSIVEMENT.**
Le contenu du plateau hermétiquement fermé a été stérilisé et restera stérile, à moins qu'il ne soit exposé à un environnement non-stérile. Stérilisé aux rayons gamma.
**ATTENTION: Lire attentivement les instructions ci-jointes avant utilisation. Avant de retourner tout produit, une autorisation préalable doit être obtenue auprès d'American Medical Systems, Inc. Avant tout retour, contacter votre représentant local AMS.**

**INHALT STERIL.**
Inhalt: eine (1) endourethrale Urolume™ Prothese mit Einführsystem
**NICHT RESTERILISIEREN.**
**ZUM EINMALGEBRAUCH.**
Der Inhalt des versiegelten Tabletts wurde sterilisiert und bleibt steril, solange das Tablett nur in einem sterilen Umfeld geöffnet wird. Durch Gammabestrahlung sterilisiert.
**VORSICHT: Vor dem Gebrauch die beiliegenden Anweisungen sorgfältig durchlesen. Eine Rücksendung dieser Produkte ist nur mit vorheriger Zustimmung der Firma American Medical Systems, Inc. gestattet. Vor Rücksendung eines Produktes sich bitte mit dem örtlichen AMS-Vertreter in Verbindung setzen.**

**CONTENUTO STERILE.**
Contenuto: una (1) protesi Urolume™ endouretrale con sistema di collocamento
**NON RISTERILIZZARE.**
**DA USARE UNA SOLA VOLTA.**
Il contenuto del vassoio sigillato è stato sterilizzato e rimane sterile, se non è esposto ad un ambiente non sterile. Sterilizzato con radiazioni gamma.
**AVVERTENZA: Leggere attentamente le istruzioni incluse prima dell'uso. Questi prodotti possono essere restituiti solo dopo aver ricevuto l'approvazione dall'American Medical Systems, Inc. Per la restituzione del prodotto contattare l'AMS Italia.**

**EL CONTENIDO ESTA ESTERILIZADO.**
Contenido: una (1) prótesis endouretral Urolume™ con dispositivo de colocación.
**NO VUELVA A ESTERILIZAR.**
**SE DEBE USAR SOLAMENTE UNA VEZ.**
El contenido de la bandeja sellada ha sido esterilizado, y se mantendrá estéril a menos que sea expuesto a un medio no estéril. Esterilizado con radiaciones gama.
**ADVERTENCIA: Lea cuidadosamente las instrucciones antes de usar el producto. Estos productos pueden ser devueltos solamente con previa autorización de American Medical Systems, Inc. Antes de devolver el producto, comuníquese con su representante local de American Medical Systems.**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113 Wicks Road
North Ryde, NSW 2113
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Fax: (61) 2-8786586





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